15-1074, -1076

IN THE

United States Court of Appeals

FOR THE FEDERAL CIRCUIT

COVIDIEN SALES LLC, COVIDIEN LP, f/k/a TYCO HEALTHCARE GROUP LP, f/k/a UNITED STATES SURGICAL CORPORATION,

Plaintiffs-Appellees,

—v.—

ETHICON ENDO-SURGERY, INC.,

Defendant-Appellant.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF CONNECTICUT,
CHIEF JUDGE JANET C. HALL, IN 14-CV-00917

CORRECTED BRIEF FOR DEFENDANT-APPELLANT [NON-CONFIDENTIAL]

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CERTIFICATE OF INTEREST

Counsel for Appellant Ethicon Endo-Surgery, Inc. certifies as follows:

1. The full name of the party I represent: Ethicon Endo-Surgery, Inc.

2. The name of the real party in interest I represent: Ethicon Endo-Surgery, Inc.

3. All parent corporations and any publicly held companies that own 10 percent of more of the stock of the parties I represent: Ethicon, Inc.; Johnson & Johnson.

4. The names of all law firms and the partners or associates that appeared for the party now represented by me in the trial court or are expected to appear in this Court:

AKIN GUMP STRAUSS HAUER & FELD LLP: Dianne B. Elderkin, Steven D. Maslowski, Barbara L. Mullin

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CONFIDENTIAL MATERIAL OMITTED

The material omitted on pages 8, 12, 25, 26, 27, 31, and 62 contains information regarding Ethicon's development and sales of the ACE+7 and information regarding sales and market share of Covidien's products.

TABLE OF AUTHORITIES

Page(s)

Cases

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Other Authorities

ABBREVIATIONS

Covidien	Plaintiffs-appellees Covidien Sales LLC, Covidien LP, and United States Surgical Corporation
Ethicon	Defendant-appellant Ethicon Endo-Surgery, Inc.
Tyco	Tyco Healthcare Group LP, now known as Covidien LP
the ‘286 patent	U.S. Patent No. 6,468,286 (the patent-in-suit)
the Davison ‘055 patent	U.S. Patent No. 5,322,055 (prior art)
ACE+7	Ethicon’s Harmonic® ACE+7® ultrasonic instrument (the accused device)

STATEMENT OF RELATED CASES

No appeal in or from the same civil action or proceeding was previously before this or any other appellate court.

Tyco Healthcare Group LP v. Ethicon Endo-Surgery, Inc., Nos. 13-1324, -1381 ("*Tyco*"), is pending in this Court and could directly affect the outcome of this appeal. The appeal in *Tyco* was argued on September 10, 2014. Chief Judge Prost and Judges Reyna and Hughes were on the panel.

Counsel is not aware of any other pending cases that would directly affect, or be directly affected by, the outcome of this appeal.

JURISDICTIONAL STATEMENT

This Court has jurisdiction over Ethicon's appeal from the preliminary injunction in this patent infringement case under 28 U.S.C. § 1292(c)(1) and would have jurisdiction of an appeal from a final judgment under 28 U.S.C. § 1295(a)(1).

Ethicon filed a timely Notice of Appeal on October 16, 2014 from the district court's Ruling re: Motion for Preliminary Injunction, which was entered on October 15, 2014, and filed a timely Notice of Appeal on October 22, 2014 from the district court's Order Granting Plaintiffs' Motion for a Preliminary Injunction and Ruling Re: Preliminary Injunction Conditions, both of which were entered on October 22, 2014.

INTRODUCTION

Ethicon appeals from the grant of a preliminary injunction against the manufacture and sale of its ACE+7 ultrasonic surgical instrument. The ACE+7 is an important new medical instrument. Because of breakthrough energy delivery technology it is the first instrument that uses ultrasonic energy to cut and seal vessels as large as 7 mm. Many surgeons regard the ACE+7 as critical to their practice and as the best choice for certain complex surgical procedures. The grant of a preliminary injunction barring the sale of this important surgical device rests on erroneous findings on likelihood of success and irreparable harm, and errors of judgment in balancing the public and private equities.

The district court's determination that Covidien is likely to succeed on the merits on obviousness rests entirely on its determination to give collateral estoppel effect to an earlier decision that is the subject of the pending merits appeal in *Tyco Healthcare Group LP v. Ethicon Endo-Surgery, Inc.*, No. 13-1324, -1381 ("*Tyco*").[1] The *Tyco* appeal was argued in this Court on September 10, 2014 and is awaiting decision.

In the *Tyco* appeal, Ethicon asserts that the district court in that case erred in finding that the sole claim asserted here, claim 15 of U.S. Patent No.

[1] Plaintiff-appellee Covidien LP was formerly known as Tyco Healthcare Group LP, which was a plaintiff in the *Tyco* case.

6,468,286 ("'286 Patent"), is not invalid. Ethicon demonstrated that the court in *Tyco* erred in analyzing obviousness when it: (1) refused to consider an Ethicon invention that the *Tyco* court held is prior art under 35 U.S.C. § 102(g), on the theory that it had not been published, and (2) distinguished another prior art reference (the Davison '055 patent), by noting that Davison '055 lacks features that are not required under the court's claim construction. In view of the substantial issues presented in the *Tyco* appeal, the district court abused its discretion in finding that the *Tyco* decision is a sufficient basis for concluding that Covidien is likely to ultimately prevail in overcoming Ethicon's obviousness defense. At a minimum, the district court should have waited until this Court decides the pending appeal in *Tyco*.

Covidien did not dispute that Ethicon's appeal in *Tyco* raises substantial issues concerning the validity of the asserted claim. Moreover, all parties agree that a decision vacating or reversing the nonobviousness determination in *Tyco* would eliminate the basis for the finding that Covidien is likely to prevail in overcoming Ethicon's obviousness defense, requiring reversal of the preliminary injunction. The district court agreed as well. It recognized that "*[i]f Ethicon ultimately succeeds [in Tyco] on its appeal on validity … then the injunction will [need to] be vacated*." A0028 (emphasis added). (Point I(A)).

The district court also erred in finding a likelihood that the ACE+7 infringes claim 15 of the '286 patent. The ACE+7 resulted from a careful effort by Ethicon to "design around" claim 15 by extending the outer tube and cutting back the sides of the clamp so that the "tissue engaging stops" defining "the proximal end of the cutting surface of the cutting jaw" are on the outer tube, rather than on the clamp as claim 15 requires. In addressing infringement, the district court erred by refusing to construe a disputed claim term ("the proximal end of the cutting surface of the cutting jaw") and compounded that error by giving that term a scope that is at odds with the patent specification. The district court further erred in concluding, on a paper record created without the benefit of discovery or cross-examination and despite a sharp dispute between the parties' experts, that notwithstanding Ethicon's design-around the ACE+7's clamp still functioned as a tissue engaging stop meeting the limitations of claim 15. (Point I(B)).

In addition, the district court erred in finding that Covidien would be irreparably harmed by sales of the ACE+7. The district court pointed to the ACE+7's curved blade as providing a "causal nexus" between the patent and Covidien's alleged harm. But in the earlier *Tyco* case, the court found after a trial that Covidien (then known as Tyco) would not be irreparably harmed by Ethicon's sale of ultrasonic instruments with a curved blade. As discussed, Ethicon then designed around claim 15 by moving the tissue stops from the clamp arm to the

outer tube, but there is no assertion that this has had any commercial impact. Covidien does not dispute that the only *commercially* significant difference between the ACE+7 and the devices at issue in *Tyco* – i.e., the ACE+7's ability to seal larger vessels – is the result of its use of an improved algorithm that results in superior accuracy in cutting and sealing. This improved algorithm and the benefits it provides are not features of the '286 patent and thus cannot provide the requisite nexus between the patent and Covidien's claimed injury. The district court erred by not giving collateral estoppel effect to the finding in *Tyco* that Covidien/Tyco is not irreparably harmed by Ethicon's sale of an ultrasonic device with a curved blade. Here, as in *Tyco*, money damages are fully adequate to compensate Covidien. (Point II).

Finally, on the facts of this case, the district court abused its discretion in granting a preliminary injunction when many surgeons prefer the ACE+7 and view it as a critical device for certain complex medical procedures; Covidien does not practice the asserted claim; and the district court failed to give appropriate weight to the public interest that favors allowing doctors and patients to benefit from an important new surgical instrument pending a determination on the merits.

The grant of a preliminary injunction should be reversed.

STATEMENT OF THE ISSUES

1. As to the likelihood of success prong of the preliminary injunction test:

   (a) Did the district court abuse its discretion in finding that Ethicon's obviousness defense is unlikely to succeed, where the court based that determination on a prior district court decision that is the subject of a pending appeal that is awaiting decision, raises substantial questions of validity and is potentially dispositive of the claim on which the preliminary injunction is sought?

   (b) Did the district court err in finding that the ACE+7 is likely to infringe, where the court refused to construe a disputed claim term, which, if construed consistent with the patent specification, supports a conclusion that the ACE+7 is likely not to infringe, and resolved a serious technical dispute between expert declarants without the benefit of expert discovery or cross-examination?

2. In granting the preliminary injunction, did the district court err in finding that sales of the ACE+7 would irreparably harm Covidien, where the court in prior litigation involving the same patent and the same kind of surgical instrument concluded after a trial that any harm to Covidien from Ethicon's sales of ultrasonic devices with curved blades is not irreparable, and where the only

additional commercial advantages of the ACE+7 are features unrelated to the invention of the patent at issue?

3. Under the circumstances of this case, did the district court abuse its discretion in granting a preliminary injunction, where the court failed to properly address the fact that the movant does not practice the patent-in-suit, and failed to give appropriate weight to the public interest that favors allowing doctors and patients to benefit from an important new surgical instrument pending a final determination on the merits?

STATEMENT OF THE CASE

When Covidien moved for the injunction at the outset of this case, the validity of the only asserted claim was the subject of a pending appeal in *Tyco Healthcare Group LP v. Ethicon Endo-Surgery, Inc.*, No. 1324, -1381. That appeal was argued in this Court on September 10, 2014 and is awaiting decision.

The evidence on the preliminary injunction motion consisted of declarations from fact witnesses and experts. Those declarations presented disputed issues on infringement, irreparable harm and the balance of hardships.

On October 15, 2014, after hearing oral argument, the district court granted Covidien's motion for a preliminary injunction. A0001-A0029. On October 22, 2014, the district court ordered Covidien to post a $5 million bond to cover the period up until December 31, 2014. A0030-A0034.

On October 27, 2014, this Court granted Ethicon's motion for an interim stay of the preliminary injunction "pending this court's ruling on [Ethicon's] motion for a stay pending appeal." Dkt. No. 10 at 2.

STATEMENT OF FACTS

A. The Parties

The parties to this case are the two "largest manufacturers of laparoscopic advanced energy surgical devices." A0019. The court in a prior case described them as "giants in the industry" and as "the Coke and Pepsi of the surgical tool market." *Tyco Healthcare Group LP v. Ethicon Endo-Surgery, Inc.*, 936 F. Supp. 2d 30, 86 (D. Conn. 2013) ("*Tyco*").

Plaintiff-appellee Covidien LP formerly was known as Tyco Healthcare Group, LP ("Tyco"). Under that name, it was a plaintiff in the *Tyco* case, which is the subject of a pending appeal in this Court, Nos. 13-1324, 13-1381.

Covidien does not sell any ultrasonic instrument with a curved blade. As the district court noted, Covidien "does not practice the ['286] patent." A0023. Covidien's reputation in the advanced energy field comes from its sale of surgical instruments using bipolar radiofrequency ("RF"). Covidien has a [redacted] market share in that field. A0636. RF devices first seal (coagulate) vessels by employing an electrical current and then cut through the vessel using a separate mechanical procedure. A0714/¶16; A1546/¶7.

Defendant-appellee Ethicon is a subsidiary of Johnson & Johnson. Ethicon is the largest and most successful maker of ultrasonic instruments that are

used in open and laparoscopic surgery, including the ACE+7. Unlike the RF devices sold by Covidien, ultrasonic devices use high frequency ultrasonic vibrations (55,000 times per second), which enable the device to simultaneously cut and seal tissue and blood vessels. A0714/¶16; A1425/¶15; A1514; A1546/¶7. Ethicon owns a seminal patent on ultrasonic instruments, the Davison '055 patent, which discloses ultrasonic surgical instruments with straight and curved blades, and teaches that the two are interchangeable.

B. The '286 Patent

1. The Background of the Invention

The '286 patent is directed to an ultrasonic surgical instrument with numerous recited components, including a curved blade and an associated clamp arm with "tissue receiving stops" positioned to stop tissue at the proximal (handle) end of the curved cutting surface.

The section of the specification entitled "Background of Related Art" explains that ultrasonic surgical instruments use high frequency vibrations to cut and coagulate tissue. A0054/col.1:22-32. Such instruments provide important benefits for surgeons and patients. Their use "facilitates faster and easier cutting of organic tissue and accelerates blood vessel clotting in the area of the cut, i.e., accelerated coagulation." *Id*. As the specification explains, ultrasonic surgical instruments were "well known" in the art. A0054/col.1:21-22.

The ultrasonic surgical instrument of the '286 patent has a blade that is curved along the instrument's longitudinal axis. As Ethicon demonstrated in the *Tyco* appeal, U.S. Patent No. 5,322,055 to Davison, which Ethicon owns and which is part of the prior art, discloses the interchangeability of straight and curved blades for ultrasonic instruments, and explains the benefits of using a curved blade.

2. The Specification's Description of the Device

The '286 specification describes an ultrasonic device that has, *inter alia*, a cutting blade 58 with a blade surface 59, an outer tube 42, and a clamp 60 with a "pair of tissue receiving stops 71." A0055/col.3:39 to col.4:1; *see also* A0056/col.5:41-67. These components can be seen in Figs. 9 and 10, which are reproduced below (A0045):

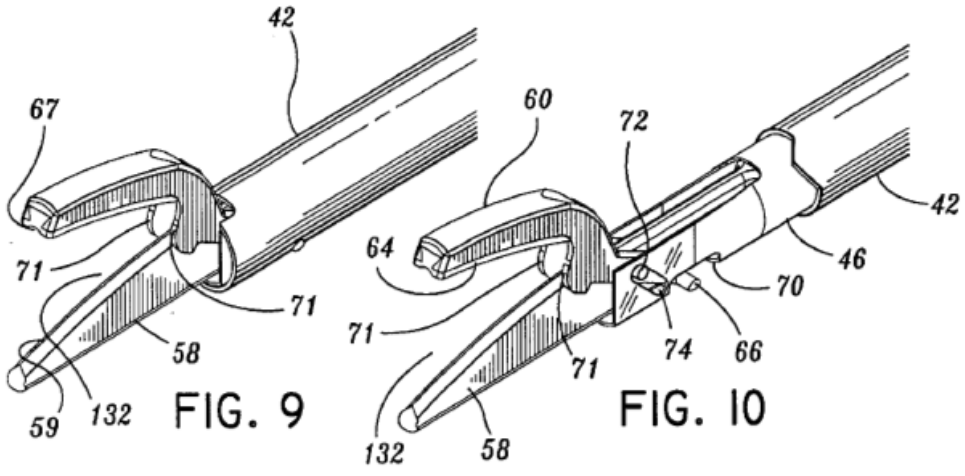


FIG. 9 FIG. 10

As described in the specification, the clamp member's "tissue receiving stops 71 … define the proximal end of the exposed blade surface 59."

A0055/col.3:67–4:1; *see also* A0056/col.5:56-58 ("The proximal end of tissue receiving area 132 is defined by tissue receiving stops 71 …."). The "[t]issue receiving stops 71 prevent tissue from moving past the proximal end of blade surface 59." A0056/col.6:35-36.

3. Asserted Claim 15

Claim 15 of the '286 patent is the only claim in issue. Claim 15 depends from claim 7. In the court below, the parties disputed infringement for the limitation in claim 7 that recites a "clamp member" having "a tissue engaging stop positioned to engage tissue and prevent positioning of tissue beyond the proximal end of the cutting surface of the cutting jaw," as further limited by the recitation in claim 15 that the "cutting surface of the cutting jaw is curved."[2]

Claims 7 and 15 are quoted below, with these limitations italicized:

> **7**. An ultrasonic instrument comprising:
>
> a) a handle assembly;
>
> b) a vibration coupler supported by and extending distally from the handle assembly;
>
> c) a cutting jaw having a cutting surface operatively connected to the vibration coupler;
>
> d) a clamp member supported adjacent to the cutting jaw, the clamp member and the cutting jaw defining a tissue receiving area, the clamp member

[2] Both sides agree that the terms "tissue engaging stops" (in claim 7) and "tissue receiving stops" (*e.g.*, at A0056/col.5:56-58) are interchangeable and have the same meaning. The same is true of the terms "cutting surface" (in claim 7) and "exposed blade surface" (*e.g.*, at A0055/col.3:67–4:1).

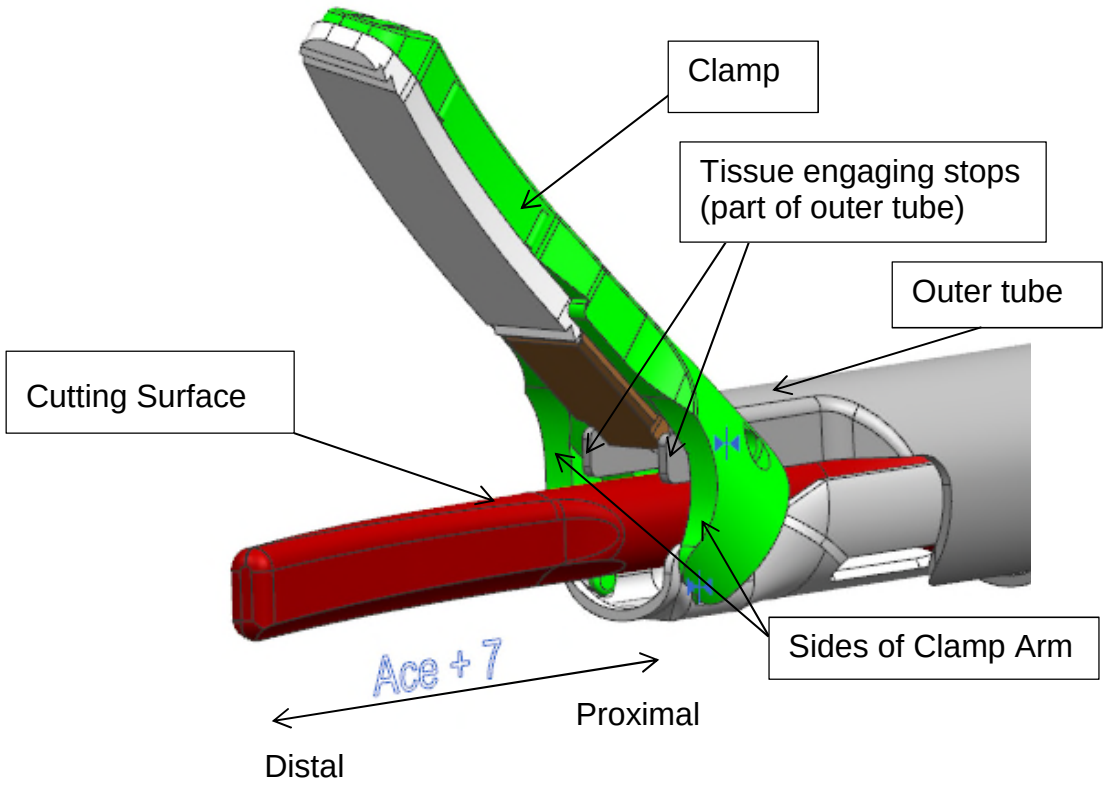
> being moveable between open and closed positions in relation to the cutting jaw and having *a tissue engaging stop positioned to engage tissue and prevent positioning of tissue beyond the proximal end of the cutting surface of the cutting jaw*.
>
> **15**. An ultrasonic instrument according to claim **7**, wherein *the cutting surface of the cutting jaw is curved* along the longitudinal axis of the instrument.

In *Tyco*, the district court construed "tissue engaging stops" as "the portions of the clamp that engage tissue and prevent tissue from moving past the proximal portion end of the blade surface." *Tyco Healthcare Group LP v. Ethicon Endo-Surgery, Inc.*, 514 F. Supp. 2d 351, 373 (D. Conn. 2007). The court adopted the plaintiff's proposed construction of "curved along the longitudinal axis" as meaning "'deviating from a straight line along the lengthwise dimension.'" *Id*. at 374. The *Tyco* court did not construe the term "proximal end of the cutting surface."

C. The ACE+7

The accused product is Ethicon's ACE+7 ultrasonic instrument. In designing the ACE+7, Ethicon deliberately "designed around" the six patent claims that the district court in *Tyco* found were valid and infringed. A1470/¶¶6-7. Ethicon spent over [redacted] and approximately [redacted] on research and development relating to this design effort. A1502/¶¶25-26.

As to claim 15, Ethicon's design-around program focused on the limitation in claim 7 (from which claim 15 depends) which recites that the instrument's clamp arm has "a tissue engaging stop positioned to engage tissue and prevent positioning of tissue beyond the proximal end of the cutting surface of the cutting jaw." The ACE+7 was designed to avoid this limitation by extending the outer tube and eliminating the convex extensions on the sides of the clamp, so that the outer tube (rather than the extensions on the clamp) functions as a tissue engaging stop to prevent tissue from moving past the proximal end of the cutting surface.



This redesign makes the ACE+7 unlike the devices in issue in the *Tyco* case, where convex extensions on the clamp were tissue engaging stops.

The ACE+7 also has new technology not found in earlier ultrasonic devices, involving an improved energy generating algorithm that is unrelated to any limitation of claim 15. Due to this algorithm the device offers superior precision in cutting and sealing vessels, allowing surgeons to cut and seal larger vessels encountered during surgery. A1470/¶5; A1495/¶8. Because of this new technology, many surgeons view the ACE+7 as critical to their practice and as the best device for certain surgical procedures. A1583/¶18; A1542.

D. The Prior *Tyco* Case

This is the third case between these parties concerning the '286 patent. In a prior case captioned *Tyco Healthcare Group LP v. Ethicon Endo-Surgery, Inc.*, No. 10-cv-0060 (D. Conn.) ("*Tyco*"), Covidien (then known as Tyco) alleged that certain ultrasonic instruments sold by Ethicon infringed the '286 patent.[3] The ACE+7 was not an accused instrument in the *Tyco* case and was introduced later. Different district court judges presided over the *Tyco* case and this case.

[3] An earlier suit by Covidien against Ethicon asserting infringement of the '286 patent was dismissed without prejudice for lack of standing, and this Court affirmed that decision. *See Tyco Healthcare Group LP v. Ethicon Endo-Surgery, Inc.*, 587 F.3d 1375 (Fed. Cir. 2009). The record from the first suit was made part of the record in the second *Tyco* action.

The *Tyco* case is important here for several reasons. First, the district court here treated the nonobviousness determination in *Tyco* as conclusive and gave that determination collateral estoppel effect when it is the subject of a pending appeal to this Court in No. 13-1324. A0005-A0006. Second, the district court here refused to give collateral estoppel effect to the determination after a trial in *Tyco* that Tyco/Covidien would *not* be irreparably harmed by Ethicon's sale of curved-blade ultrasonic instruments that practice claim 15. A0017. On a paper record and without discovery, the district court here reached the opposite conclusion. A0018-A0021.

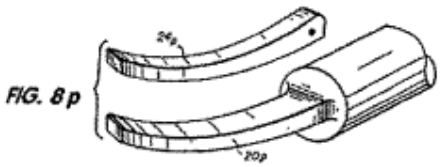
1. The District Court's Rulings in *Tyco*

a. The *Tyco* Court's Determination on Obviousness

In *Tyco*, Covidien accused Ethicon of infringing 32 patent claims. Ethicon raised validity defenses based on the prior art. After a trial on the merits, the district court found that: (i) Ethicon engineers had conceived a prototype ultrasonic device prior to Tyco's invention; (ii) Ethicon was diligent in reducing that prototype ultrasonic device to practice; and (iii) that prototype was not abandoned, suppressed or concealed. *Tyco Healthcare Group LP v. Ethicon Endo-Surgery, Inc.*, 936 F. Supp. 2d 30, 61-75 (D. Conn. 2013). The court accordingly concluded (correctly) that the Ethicon had a prior invention meeting all of the requirements for prior art under 35 U.S.C. § 102(g). 936 F. Supp. 2d at 75-76.

The district court also concluded (correctly) that this § 102(g) prior art anticipates 26 of the 32 asserted claims. 936 F. Supp. 2d at 76.

The district court in *Tyco* found that Ethicon's prior invention lacked a curved blade and therefore did not anticipate claims on an ultrasonic device with a "curved blade," such as claim 15.[4] But Ethicon demonstrated that Davison '055 discloses a curved blade for an ultrasonic instrument, as shown on the right, and teaches that straight and curved blades are interchangeable for such instruments.



The *Tyco* court should have concluded that claim 15 is obvious in view of Ethicon's prior § 102(g) invention and Davison '055. But the court erroneously refused to treat the § 102(g) prior invention as prior art for obviousness. Instead, it concluded, for reasons not advocated by anyone, that only work "published" before the claimed invention was conceived can be treated as prior art for obviousness under § 102(g).[5] 936 F. Supp. 2d at 62.

The *Tyco* court compounded that error by distinguishing Davison '055 on the ground that its curved blade functions differently from the curved blade that

[4] The six remaining claims in *Tyco* also included claims on an ultrasonic device with a "dual camming" mechanism. The "dual cam" claims were not asserted here as a basis for the preliminary injunction and are not relevant to this appeal.

[5] There is no dispute that Ethicon's § 102(g) invention was subsequently disclosed in U.S. Patent No. 5,980,510.

is described in the specification of the '286 patent. *Id*. at 66-68. That was error because the court's construction of "curved along the longitudinal axis" in claim 15 encompasses *any* "deviation from a straight line along the lengthwise dimension," and is not limited to curved blades that function in a particular manner. *Tyco*, 514 F. Supp. 2d at 374. In effect, the court gave the claims a narrower scope for obviousness than for infringement.

b. The Denial of a Permanent Injunction in *Tyco*

The court in *Tyco* denied Tyco/Covidien's request for a permanent injunction against Ethicon's sale of ultrasonic instruments with a curved blade that practice claim 15. In so doing, the court properly concluded that any harm to Tyco/Covidien was not irreparable and that "'remedies available at law, such as monetary damages,' are fully adequate to compensate for Tyco's injury." *Tyco*, 936 F. Supp. 2d at 85-86.

The *Tyco* court also recognized that an injunction "would pull many devices that are presently used in surgery off the market," and described this as "an important consideration …." *Id*. at 86. The court concluded that the "balance of hardships does not tip sufficiently in Plaintiff's favor to warrant … [the] extreme remedy [of a permanent injunction]." *Id*.

The *Tyco* court also denied Tyco's claim for lost profits damages. After a trial, the court found that surgeons generally view the RF devices sold by

Tyco (now Covidien) as having "recognized cutting deficiencies" and stated there was "no evidence [that] … surgeons would have simply converted to [Covidien's] RF devices" if Ethicon's ultrasonic devices had not been available. *Id.* at 78.

2. The Pending *Tyco* Appeal

Ethicon appealed from the *Tyco* court's rejection of its obviousness defenses. Tyco cross-appealed from judgment of anticipation of certain claims and from the denial of a permanent injunction. The *Tyco* appeal was argued on September 10, 2014 before Chief Judge Prost and Judges Reyna and Hughes.

a. Ethicon's Appeal on Obviousness

On appeal, Ethicon demonstrated that the *Tyco* court committed two basic errors in rejecting its obviousness defense for the "curved blade" claims, including claim 15.

First, the *Tyco* court's refusal to treat Ethicon's prior invention as prior art is at odds with case law holding that § 102(g) prior art is prior art for obviousness, as well as for anticipation. *See Aventis Pharma Deutschland GmbH v. Lupin, Ltd.*, 499 F.3d 1293, 1300 (Fed. Cir. 2007); *E.I. du Pont de Nemours & Co. v. Phillips Petroleum Co.*, 849 F.2d 1430, 1436-37 (Fed. Cir. 1988); *Kimberly-Clark Corp. v. Johnson & Johnson*, 745 F.2d 1437, 1444 (Fed. Cir. 1984).

Second, the *Tyco* court erred in distinguishing Davison '055 by giving the "curved blade" claims, including claim 15, a narrower scope when determining

validity than it did in determining infringement. "It is axiomatic that claims are construed the same way for both invalidity and infringement." *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1330 (Fed. Cir. 2003). [6]

On appeal in *Tyco*, Ethicon demonstrated that when Ethicon's § 102(g) prior invention is correctly treated as prior art for obviousness, and the claims are given the same scope for obviousness that they were given for infringement, the "curved blade" claims, including claim 15, would have been an obvious combination of Ethicon's § 102(g) invention and Ethicon's own Davison '055 patent.

b. Tyco's Cross-Appeal from the Denial of a Permanent Injunction

In opposing the cross-appeal from the denial of a permanent injunction, Ethicon demonstrated that the *Tyco* court was correct in concluding that Tyco/Covidien would not be irreparably harmed by Ethicon's sale of ultrasonic instruments with a curved blade, and in finding that the other equitable factors did not warrant an injunction.

E. Proceedings in the District Court

The appeal in the *Tyco* case was pending when Covidien moved for a preliminary injunction in this case. By the time the district court granted the

[6] These issues are discussed in greater detail in Ethicon's appeal brief in *Tyco* at pages 33-50, and in its reply brief at pages 13-25.

preliminary injunction that is the subject of this appeal, the *Tyco* appeal had been argued six weeks earlier and was awaiting decision.

The evidence on the preliminary injunction motion consisted of declarations from fact witnesses and experts. Those submissions raised fact disputes on infringement, irreparable harm and the balance of hardships. The district court decided those fact disputes on the papers and oral argument.

1. The District Court's October 15, 2014 Decision

On October 15, 2014, the district court entered a decision granting the preliminary injunction. A0001-A0029.

a. Likelihood of Success

As to validity: In addressing likelihood of success on validity, the district court relied solely on the *Tyco* decision, which is the subject of the pending appeal. A0005. It gave that decision collateral estoppel effect, stating that "Ethicon is precluded from challenging claim 15's validity because [the] district court judgment [in *Tyco*] is final for purposes of issue preclusion." *Id*.

Although Ethicon did not dispute that collateral estoppel barred it from re-litigating obviousness at this juncture, it pointed out that the pending appeal in *Tyco* "raises a substantial question of invalidity" for claim 15, A1402, which renders the *Tyco* decision insufficient to establish that Covidien is "'likely to

succeed at trial on the validity issue.'" *Id.* (quoting *Titan Tire Co. v. Case New Holland, Inc.*, 566 F.3d 1372, 1377 (Fed. Cir. 2009)).

Covidien did not dispute that the *Tyco* appeal raises substantial issues concerning the validity of claim 15. The district court did not address that issue, but did note (correctly) that "*[i]f Ethicon ultimately succeeds on its appeal [in Tyco] on validity … then the injunction will [have to] be vacated ….*" A0028 (emphasis added).

In opposing the preliminary injunction, Ethicon urged the district court to "consider delaying its decision while the [*Tyco*] appeal is pending." A1404. This would have given the district court the benefit of knowing whether this Court will affirm or reverse in *Tyco*. The district court did not adopt that approach. Instead, it treated Ethicon's suggestion as a motion for a stay, which it then denied. A0028.

As to infringement: In their respective declarations, both sides' experts agreed that the ACE+7 was redesigned to have tissue stops on its outer tube and that these tissue stops extend distally (toward the distal end of the blade) past the sides of the clamp. A1437-A1438/¶46; A1167/¶46; A1169/¶51; A1170-A1171/¶53. But they disagreed sharply on the issue of infringement. Covidien's expert Dr. Durfee asserted that the sides of the ACE+7's clamp *also* stop tissue from moving past the proximal end of the cutting surface, and thus meet the

limitations of claim 15. A1169-A1171/¶¶49-54. Dr. Durfee stated that he had "observed" this in tests he performed on chamois and animal tissue with the ACE+7 device. *Id.*

Ethicon's expert Dr. Cimino identified three separate flaws in Dr. Durfee's analysis. First, Dr. Durfee ignored the fact that according to the '286 patent, the tissue stops define the proximal end of the cutting surface. A1440/¶49. To illustrate that the proximal end of the ACE+7's cutting surface is defined by the outer tube tissue stops, Dr. Cimino ran a piece of paper along the cutting surface – a test that Dr. Durfee himself had described in the *Tyco* trial – and showed that it was stopped by the outer tube, not the clamp. A1440-A1442/¶¶49-52. Because the sides of the clamp are located beyond (proximal to) this location, they cannot stop tissue from moving beyond the proximal end of the cutting surface as claim 15 requires. A1442-A1443/¶¶53-54.

Second, Dr. Cimino noted that regardless of how the "proximal end of the cutting surface" is defined, neither Dr. Durfee nor anyone else could "observe" the sides of the clamp stopping tissue from moving beyond it in the ACE+7 device, because the cutting surface and the outer tube tissue stops are obscured from view in Dr. Durfee's tests. A1446-A1447/¶¶60-62. In fact, Dr. Cimino explained, because the outer tube tissue stops not only extend further out (more distal) than the clamp, but are also positioned inside the clamp, immediately adjacent to the

cutting surface, the outer tube, not the clamp, necessarily is the structure that prevents tissue from moving *along the cutting surface*. A1444-A1447/¶¶56-63. The sides of the clamp, which are positioned outside the outer tube, can only engage tissue along the sides of the blade, which does not satisfy claim 15. *Id.*

Third, Dr. Cimino pointed out that claim 15, in addition to reciting that the tissue stop prevent tissue from moving "beyond the proximal end of the cutting surface of the cutting jaw," further recites that "*the cutting surface of the cutting jaw is curved* …." A0057/col.8:45 (emphasis added). Because the curvature in the ACE+7 blade ends well before the sides of the clamp, the sides of the clamp cannot stop tissue from moving past the end of the curved cutting surface. A1447-A1449/¶¶64-67.

In his reply declaration, Dr. Durfee disagreed with Dr. Cimino's opinions, but provided new analysis only with respect to Dr. Cimino's paper demonstration. According to Dr. Durfee, he had been able to slip a portion of a sheet of paper beneath the tissue stops on the ACE+7's outer tube to contact the clamp. A1653-A1655/¶¶7-10. Although Dr. Durfee purported to contradict Dr. Cimino's demonstration, he did not attempt to explain the discrepancy. In fact, it is apparent from Dr. Durfee's photographs that he angled the paper, so that one corner slipped beneath one side of the outer tube on the side of the blade, while the other corner was stopped by the other. *Id.*; A1781-A1782.

The expert declarations thus created a sharp dispute on infringement. The district court resolved that dispute on the paper record, without expert discovery, depositions, or an evidentiary hearing, and found that Covidien had established a likelihood of success on infringement. A0008-A0016.

The district court rejected Ethicon's assertion that claim construction was needed for the phrase "proximal end of the cutting surface." A0008. Although it rejected Ethicon's proposed construction of the "proximal end of the cutting surface" as being "define[d]" by the tissue stops, A0010-A0013, the court did not construe that term.

The district court also rejected Ethicon's evidence that the tissue stops on the ACE+7's outer tube, not the sides of the clamp, prevent tissue from moving along the cutting surface. A0013-A0014. Relying on the paper tests described in Dr. Durfee's reply declaration, the court stated that although it "is true both that the outer tube protrusions extend distally beyond the clamp ears and that they are closer or more adjacent to the blade surface than the clamp ears," there are still "gaps between the outer tube protrusions and the blade surface" that would allow tissue to "squeeze through the gaps between the outer tube protrusions, slide along the blade, and ultimately press against the clamp ears." A0014.

Finally, as to Dr. Cimino's third point, the district court held that claim preclusion barred Ethicon from asserting that the clamp did not prevent

tissue from moving past the end of the curved cutting surface – despite expressly holding elsewhere that preclusion did *not* apply because the ACE+7 is different from the devices at issue in the previous trial. A0014-A0016. The court further stated that because the ACE+7's "blade as a whole" is curved, it did not matter that the *cutting surface* of the blade is not curved at the location where the clamp allegedly stops tissue, notwithstanding the fact that claim 15 expressly recites a curved "cutting surface," not a curved "blade." A0016.

b. Irreparable Harm

The district court refused to give collateral estoppel effect to the *Tyco* court's determination after a trial that any harm to Tyco/Covidien from Ethicon's sales of curved blade ultrasonic instruments that practice claim 15 is not irreparable and can be "fully" compensated by "'remedies available at law, such as monetary damages.'" *Tyco*, 936 F. Supp. 2d at 86. Instead, the district court allowed Covidien to re-litigate the issue here. Its conclusion on the paper record was directly contrary to the conclusion that the *Tyco* court reached after a full trial. A0018-A0022.

The district court accepted an equivocal assertion by Covidien's Director of Global Marketing, Mr. Chindlund, that Covidien "'*could* lose as much as 5 to 10 percentage points of market share of the vessel sealing and dissection market in the next 12 month[s] *if* Ethicon is effective in targeting the … ACE+7

against Covidien's LigaSure product line.'" A0020 (emphasis added). The court did not address undisputed evidence showing that a substantial majority of ACE+7 sales would be [redacted]. A1497/¶16; A1828-A1829/¶6.

The district court did note that Covidien and Ethicon sell different types of advanced energy devices (RF for Covidien versus ultrasonic for Ethicon). A0019. However, it never addressed the differences in these devices and physicians' perceptions of those differences, even though they led the *Tyco* court to reject the assertion that sales of Ethicon's ultrasonic devices would cause Covidien to lose sales and profits on RF devices. *Tyco*, 936 F. Supp. 2d at 78.

The district court's later decision dated October 22, 2014 reflects its measure of the extent of Covidien's possible harm. In setting a $5 million bond under FED. R. CIV. P. 65(c) to secure the injunction through the end of 2014, the district court found that Ethicon expected to realize incremental profits of at least [redacted] from U.S. and foreign sales of the ACE+7 in the period between October 22, 2014 and the end of the year. A0002. If anything, the [redacted] figure overstates the profits Covidien would lose because some sales of the ACE+7 would come at the expense of other competitors whose market share is approximately [redacted] the size of Covidien's. *See* A0019.

The [redacted] number should be considered in the context of Covidien's business as a whole. As the district court found, Covidien is one of the "two largest manufacturers of laparoscopic advanced energy surgical devices." A0019. It is a "giant" in the industry. *Tyco*, 936 F. Supp. 2d at 86. Its sales of LigaSure RF devices total more than [redacted] annually, and that is only part of Covidien's overall business. A0636/¶14. Covidien's potential lost sales in this case would only be [redacted] of its total sales.

In addition to lost market share, the district court also accepted the assertion by Covidien's Director of Global Marketing that sales of the ACE+7 would "falsely give[ ] consumers the impression that Ethicon was the innovator [of ultrasonic devices with a curved blade]." A0020-A0021. In doing so, the district court ignored the fact that the prior art Davison '055 patent – which Ethicon owns – discloses such devices, so Ethicon can properly claim to have innovated that feature. The court also did not explain why the ACE+7 would convey this "impression" to a greater extent than the ultrasonic instruments with curved blades that were at issue in *Tyco* and were found *not* to cause any irreparable harm to Covidien. *Tyco*, 936 F. Supp. 2d at 86.

The district court also addressed the "nexus" requirement for irreparable harm, and found that the ACE+7's curved blade provides a nexus between Covidien's harm and claim 15. A0021. But the ultrasonic instruments in

Tyco also had a curved blade and were found *not* to cause Covidien any irreparable harm. *Tyco*, 936 F. Supp. 2d at 86. Meanwhile, undisputed evidence showed that the only commercially significant difference between the ACE+7 and the earlier devices in the *Tyco* case – i.e., the ACE+7's ability to treat larger vessels through the use of an improved energy generating algorithm – is not a feature of claim 15 and therefore cannot provide the requisite nexus between the alleged injury and the patent. *See* A1405-A1407; A1470/¶5; A1495/¶8; A1551-A1552/¶¶25-26. The district court did not address this evidence.

c. The Public Interest

Covidien relied on the public interest in enforcing valid patents, which is present in every patent case and is often deemed secondary to public health concerns when medical technology is involved. *See, e.g.*, *Datascope Corp. v. Kontron Inc.*, 786 F.2d 398, 401 (Fed. Cir. 1986) ("the public [would] be harmed by an injunction [against a medical product] that some physicians prefer"); *Cordis Corp. v. Boston Scientific Corp.*, 99 F. App'x 928, 935 (Fed. Cir. 2004) ("[A] strong public interest supports a broad choice of drug-eluting stents ….").

Ethicon offered evidence that many doctors prefer the ACE+7 and view it as a critical instrument for certain medical procedures. A1583/¶18; A1542; A1933-A1934/¶¶5-8. Dr. Robert Zurawin, Chief of Minimally Invasive Gynecologic Surgery at Baylor College of Medicine, described the ACE+7 as

"revolutionary" and as "integral to" his practice. A1933/¶5. He explained that by combining larger vessel sealing capabilities with the benefits of ultrasonic energy, the ACE+7 increases efficiency and reduces risks, which is beneficial to patient outcomes. A1933-1934/¶¶6-7; *see also* A1582-A1583/¶¶16-17.

Ethicon also demonstrated that neither Covidien nor any other company offers an adequate substitute for the ACE+7. A1583/¶¶18-19; A1933-A1934/¶¶7-8; A1501/¶22. Covidien does not practice the claim 15 invention and it does not sell any ultrasonic instrument capable of sealing and cutting vessels up to 7 mm. Covidien also failed to establish that the Olympus Thunderbeat – a straight-bladed device that uses a combination of ultrasonic and RF energy modalities – is an adequate substitute for the ACE+7 because in ultrasonic-only mode it cannot cut and seal larger vessels. *See* A1581¶¶11, 19; A1501/¶22; A1934/¶8.

The district court acknowledged that "some physicians may prefer the ACE+7 over other devices," and that this is "an important public interest factor …." A0026. It stated that "the Federal Circuit has recognized that there is a strong public interest in the availability of medical products." A0024-A0025 (citing *Datascope*, 786 F.2d at 401; *Cordis*, 99 F. App'x at 935).

The district court acknowledged that an injunction would frustrate the "strong public interest in the availability of medical products," A0024, but stated that this "harm to the public" would be "limited by the fact that the ACE+7 is a

new device ….” A0026. The district court did not explain why this consideration would in any way lessen the harm to the public from an injunction barring sales of the ACE+7 when it is undisputed that the ACE+7 is superior to earlier ultrasonic devices and when ultrasonic devices provide more precise cutting and sealing than RF devices. The court also stated that the harm to the public would be “limited … by the availability of alternative devices,” *id.*, even though there are no other ultrasonic instruments capable of sealing and cutting large vessels and, as a result, many physicians do not consider those other devices to be acceptable substitutes for the ACE+7. A1583/¶¶18-19; A1933-A1934/¶¶7-8; A1501/¶22.

d. The Balance of Equities

In addressing the balance of hardships, Covidien relied on the same injury that made up its alleged irreparable harm. Ethicon offered evidence that a preliminary injunction not only would cause it to lose profits, but also would injure its good will and reputation by requiring it to discontinue sales of a surgical instrument that many physicians rely upon, and that these harms outweigh Covidien’s harm from having to compete against the ACE+7. A1502-A1503/¶27; A1924-A1925/¶3; A1928/¶¶17-18.

Ethicon’s internal forecasts, prepared in the ordinary course of its business, show that after netting out the sales that the ACE+7 would take away from other Ethicon devices, the total incremental revenues from U.S. sales of the

ACE+7 would be approximately [redacted] in 2014, [redacted] in 2015, and [redacted] in 2016. A1875-A1876/¶¶13-15. In comparison, Covidien has more than [redacted] in annual sales of LigaSure RF devices. A0636/¶14.

The district court found that both sides would suffer hardships from an adverse ruling. A0023. However, it concluded that the balance of equities favored Covidien, even though Covidien "does not practice the ['286] patent" and does not sell any ultrasonic device with a curved blade. *Id*.

2. The District Court's October 22, 2014 Decision

After the district court entered its October 15, 2014 decision, Ethicon sought a $300 million bond to protect it from the tangible and intangible harms it would suffer from an improvidently granted injunction in the period until the trial. A1862; A1866-A1869. Covidien proposed a $3 million bond to cover Ethicon's lost profits through the end of 2014, with nothing to cover the cost of discontinuing and then re-launching the ACE+7 and nothing to cover injuries that are less quantifiable. A1850-A1851. Covidien told the district court that it did not propose a bond for the period after December 31, 2014 because it "reasonably expects [this Court] to rule on Ethicon's proposed expedited appeal [in this case]" by the end of 2014. A1850 at 1 n.1.

On October 22, 2014, the district court ordered Covidien to post a $5 million bond to secure the injunction "through December 31, 2014 …." A0031-

A0032. The court stated that "[i]f the Federal Circuit has not ruled claim 15 of the '286 patent invalid in the *Tyco* litigation by that time, the court will revisit the bond amount at the end of the year." A0032.

In its October 22 decision, the district court acknowledged that the *Tyco* appeal presents an "important" validity issue that "bears heavily on the rights of the parties." A0034. Instead of addressing that important validity issue, the district court left it to this Court to do so. As the district court stated, "[i]f there are substantial questions as to the validity of claim 15 of the '286 patent, the Federal Circuit will limit the harm to Ethicon by staying or, ultimately, vacating the injunction." *Id.*

SUMMARY OF ARGUMENT

This Court should reverse the grant of a preliminary injunction.

In addressing likelihood of success for validity, the district court gave the prior determination of nonobviousness in *Tyco* preclusive effect. But the *Tyco* decision does not give Covidien a likelihood of prevailing at trial on obviousness when the *Tyco* appeal is pending and raises serious issues. Regardless of whether the district court was correct in applying collateral estoppel, the basis for finding likelihood of success would disappear if *Tyco* is reversed in the pending appeal. (Point I(A)).

The district court also erred in finding a likelihood that the ACE+7 infringes claim 15. In reaching that conclusion, the district court failed to give the term the "proximal end of the cutting surface of the cutting jaw" a scope and meaning that is consistent with its meaning in view of the patent specification, and erred in finding that Covidien had shown a likelihood of infringement when the infringement issues were hotly disputed by the parties' experts. (Point I(B)).

In addressing irreparable harm, the district court erred by allowing Covidien to re-litigate the earlier determination in *Tyco* that any harm to Tyco/Covidien from Ethicon's sale of ultrasonic instruments with a curved blade is not irreparable and could be remedied by money damages. That was inappropriate when the only commercially significant difference between the ACE+7 and the

instruments at issue in *Tyco* – an improved algorithm that enables the ACE+7 to treat larger vessels – is not a feature of claim 15 and cannot provide the requisite causal nexus between Covidien's harm and the alleged infringement. (Point II).

Finally, weighing all of the equities, it was an abuse of discretion to order a preliminary injunction against a surgical instrument that many doctors view as critical to their practice and as the best choice for certain medical procedures, particularly when Covidien does not practice claim 15 and does not sell a similar ultrasonic instrument. (Point III).

ARGUMENT

STANDARD OF REVIEW

"On an appeal from the grant of a preliminary injunction, [this Court] review[s] the district court's legal rulings *de novo* and its ultimate decision to grant a preliminary injunction for abuse of discretion." *Apple Inc. v. Samsung Elecs. Co., Ltd.*, 695 F.3d 1370, 1373 (Fed. Cir. 2012).

"A district court abuses its discretion [in granting an injunction] when it acts 'based upon an error of law or clearly erroneous fact findings' or commits 'a clear error of judgment.'" *Robert Bosch LLC v. Pylon Mfg. Corp.*, 659 F.3d 1142 1147 (Fed. Cir. 2011) (quoting *Ecolab, Inc. v. FMC Corp.*, 569 F.3d 1335, 1352 (Fed. Cir. 2009)).

Issues of claim construction are reviewed *de novo*. *Lighting Ballast Control LLC v. Philips Elecs. N. Am. Corp.*, 744 F.3d 1272, 1276-77 (Fed. Cir. 2014) (en banc).

THE STANDARD AND BURDENS ON A PRELIMINARY INJUNCTION MOTION

This Court "applies the law of the regional circuit" when reviewing the grant or denial of a preliminary injunction. *Aevoe Corp. v. AE Tech. Co., Ltd.*, 727 F.3d 1375, 1382 (Fed. Cir. 2013). It is well settled in the Second Circuit that a preliminary injunction "'is an extraordinary and drastic remedy, one that should not be granted unless the movant, by a clear showing, carries the burden of

persuasion.'" *Moore v. Consolidated Edison Co. of N.Y.*, 409 F.3d 506, 510 (2d Cir. 2005) (Sotomayor, J.) (quoting *Mazurek v. Armstrong*, 520 U.S. 968, 972 (1997)); *see also LifeScan Scotland, Ltd. v. Shasta Techs., LP*, 734 F.3d 1361, 1366 (Fed. Cir. 2013) (same). In deciding preliminary injunction motions courts should proceed with caution because their decisions are rendered "'before the issues of fact and law have been fully explored and finally resolved ….'" *Abbott Laboratories v. Sandoz, Inc.*, 544 F.3d 1341, 1344-45 (Fed. Cir. 2008) (quoting *Univ. of Texas v. Camenisch*, 451 U.S. 390, 395 (1981)).

The test for a preliminary injunction is well settled. "A plaintiff seeking a preliminary injunction must establish [1] that [it] is likely to succeed on the merits, [2] that [it] is likely to suffer irreparable harm in the absence of preliminary relief, [3] that the balance of equities tips in [its] favor, and [4] that an injunction is in the public interest." *Astrazeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1049 (Fed. Cir. 2010) (quoting *Winter v. Natural Res. Def. Council*, 555 U.S. 7, 21 (2008)). "If the accused infringer 'raises a substantial question concerning infringement or validity,' then the patentee has not established that it is likely to succeed on the merits, and a preliminary injunction is not appropriate." *LifeScan*, 734 F.3d at 1366 (quoting *Amazon.com., Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1350-51 (Fed. Cir. 2001)).

To establish a likelihood of success on the merits, "[a] patentee seeking a preliminary injunction in a patent infringement suit must show that it will likely prove infringement, and that it will likely withstand challenges, if any, to the validity of the patent." *Titan Tire*, 566 F.3d at 1376. The movant "must persuade the court that, despite the challenge presented to validity, the patentee nevertheless is likely to succeed at trial on the validity issue." *Id.* at 1377. The movant "bears the ultimate burden of establishing a likelihood of success on the merits with respect to the patent's validity." *Altana Pharma AG v. Teva Pharms. USA, Inc.*, 566 F.3d 999, 1005 (Fed. Cir. 2009).

To show irreparable harm, a movant must show harm not compensable by money damages that is "actual and imminent, not remote or speculative." *Kamerling v. Massanari*, 295 F.3d 206, 214 (2d Cir. 2002); *see also Grand River Enterprise Six Nations, Ltd. v. Pryor*, 481 F.3d 60, 66 (2d Cir. 2007).

POINT I

THE DISTRICT COURT ERRED IN FINDING THAT COVIDIEN HAS A LIKELIHOOD OF SUCCESS

The district court erred in finding that Covidien is likely to prevail at trial on the issues of validity and infringement.

A. Validity

1. The Earlier Decision in *Tyco* Was Not Enough to Establish That Covidien is Likely to Ultimately Prevail on Validity

In asserting that it is likely to succeed on obviousness, it was not enough for Covidien to rely on the district court decision in *Tyco*. Covidien needed to show that it is "likely to succeed *at trial* on the validity issue." *Titan Tire*, 566 F.3d at 1377 (emphasis added). It needed to demonstrate a "likelihood of ultimate success on the merits." *Doran v. Salem Inn, Inc.*, 422 U.S. 922, 932 (1975). The district court decision in *Tyco* does not give Covidien a likelihood of "ultimate success on the merits," *id.*, when the appeal in *Tyco* is pending and raises substantial validity issues.

"The precedent of this court holds that if the accused infringer 'raises a "substantial question" concerning validity, enforceability, or infringement (*i.e.*, asserts a defense that [the movant] cannot show lacks "substantial merit") the preliminary injunction should not issue.'" *Altana*, 566 F.3d at 1006 (quoting *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1364 (Fed. Cir. 1997)); *see*

also Astrazeneca LP v. Apotex, Inc., 633 F.3d 1042, 1050 (Fed. Cir. 2010) ("A preliminary injunction should not issue if an alleged infringer raises a substantial question of infringement or validity, *i.e.*, the alleged infringer asserts an infringement or invalidity defense that the patentee has not shown lacks substantial merit."); *LifeScan*, 734 F.3d at 1366 (same).

Here, Ethicon demonstrated that the *Tyco* appeal raises "a substantial question" concerning the validity of claim 15. *Astrazeneca*, 633 F.3d at 1050. *See* A1403. Covidien did not dispute this. As Ethicon argued in the *Tyco* appeal, the *Tyco* court erred: (1) in refusing to treat Ethicon's § 102(g) prior invention as prior art for obviousness; and (2) in relying on features that are not part of the construction of "curved blade" to distinguish the Davison '055 patent. *See supra* pp. 18-19. When the curved blade claims are given the same scope for obviousness as for infringement, and Ethicon's § 102(g) prior invention is correctly treated as prior art for obviousness, claim 15's subject matter would have been obvious to a person of ordinary skill in the art, making claim 15 invalid as a matter of law.

Covidien never tried to demonstrate that the *Tyco* appeal "lacks substantial merit." *Astrazeneca*, 633 F.3d at 1050. It did not meet its burden of demonstrating that it has a likelihood of "ultimate success on the merits," *Doran*,

422 U.S. at 932, and the injunction accordingly "should not [have] issue[d] …." *Astrazeneca*, 633 F.3d at 1050.

2. The District Court Made a Clear Error in Judgment in Issuing the Injunction While the *Tyco* Appeal Is Pending

In opposing the motion for a preliminary injunction, Ethicon urged the district court to "delay[ ] its decision [on the preliminary injunction motion] while the [*Tyco*] appeal is pending." A1405. If the district court had done so, it would have had the benefit of knowing whether this Court will affirm or reverse the validity decision in *Tyco*.[7]

The district court made a clear error in judgment in issuing the preliminary injunction when the *Tyco* appeal already had been argued and is pending in this Court. That error is egregious because the injunction – barring the sale of a medical device that many surgeons view as critical for certain medical procedures – has an adverse effect on doctors and patients, and Covidien does not sell a similar ultrasonic instrument.

At a minimum, the district court should have considered the possibility that this Court might reverse in *Tyco* when it balanced the equities. But

[7] *See* 18A CHARLES ALAN WRIGHT ET AL., FEDERAL PRACTICE AND PROCEDURE 2d § 4433 at 88 (2002) (recommending "delaying further proceedings in the second action pending conclusion of the appeal in the first action" because of the "[s]ubstantial difficulties result from the rule that a final trial-court judgment operates as res judicata while an appeal is pending").

the district court did not do that either. In a case involving an important medical device, the district court's failure to wait for this Court's decision in *Tyco* and its failure to address the possibility of a reversal in *Tyco* were clear errors of judgment and an abuse of discretion.

3. The District Court Decision in *Tyco* Does Not Control the Outcome Here

A reversal in *Tyco* would eliminate the foundation for the district court's determination of likelihood of success and require reversal of the preliminary injunction. The district court recognized this when it stated that "*[i]f Ethicon ultimately succeeds [in* Tyco*] on its appeal on validity … then the injunction will [need to] be vacated*." A0028 (emphasis added).

If the *Tyco* decision is vacated or reversed in the pending appeal, the preliminary injunction must fall with it. "It is well established that an injunction must be set aside when the legal basis for it has ceased to exist." *ePlus, Inc. v. Lawson Software, Inc.*, 760 F.3d 1350, 1355 (Fed. Cir. 2014) (vacating an injunction that was based on patent claims later found invalid).

This is true regardless of whether the district court was correct in applying collateral estoppel earlier. *Butler v. Eaton*, 141 U.S. 240, 242 (1891) makes this clear. *Id.* (reversing second judgment upon reversal of underlying judgment, even though there was "[no] error in the [application of collateral estoppel] in the judgment now before us"). Under *Butler*, whether the district court

was correct or incorrect in applying collateral estoppel is of no moment if the predicate decision is reversed. *See also Ill. Central R. Co. v. Olberding*, 214 F.2d 91 (7th Cir. 1954) (same). As this Court stated in *Levi Strauss & Co. v. Abercrombie & Fitch Trading Co.*:

> Dating back to at least to *Butler v. Eaton*, 141 U.S. 240, 242-44 … (1891), a bedrock principle of preclusion law has been that a reversed judgment cannot support preclusion; indeed, "a second judgment based upon the preclusive effects of the first judgment should not stand if the first judgment is reversed." 18A Charles A. Wright, et al., Federal Practice and Procedure, § 4433 (2d ed. 2002) (footnote omitted); § 4427 at 5 ("Should the judgment be … reversed on appeal, however, res judicata [in the sense covering both preclusion doctrines] falls with the judgment.") ….

719 F.3d 1367, 1372 (Fed. Cir. 2013). Under *Levi Strauss*, "a [preliminary injunction] based upon the preclusive effects of the [*Tyco*] judgment should not stand if the [*Tyco*] judgment is reversed." *Id*.; *see also Mendenhall v. Barber-Greene Co.*, 26 F.3d 1573 (Fed. Cir. 1994) (reversing an injunction based on patents that this Court found invalid in a co-pending appeal, and stating that it would be "anomalous in the extreme" to uphold an injunction in connection with patents this Court has held invalid).

B. The District Court Erred in Finding that Covidien Has a Likelihood of Success on Infringement

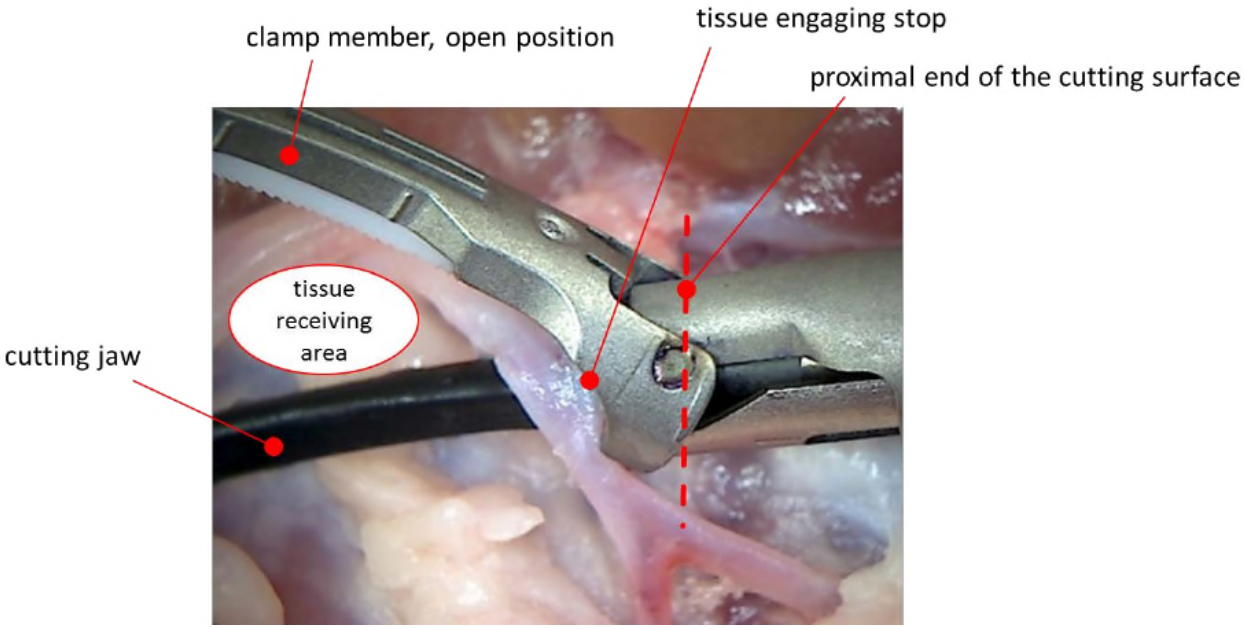
In designing the ACE+7, Ethicon engineers deliberately sought to design around claim 15. As discussed above, to achieve that goal they cut back the

sides of the clamp and extended the outer tube so that the tissue engaging stops on the device are on the outer tube, rather than on the clamp member as required by claim 15. *See supra* pp. 12-14; A1482-1487/¶¶ 21-25 & Figs. J, L-M.

Although the district court recognized that the parties' expert witnesses "fiercely dispute[d]" whether Ethicon's design around effort had succeeded in avoiding infringement, A0008, it concluded on a paper record that the ACE+7 was likely to infringe. A0008-A0016. For multiple reasons, this was error.

1. The District Court Erred in Refusing to Construe Claim 15 Consistent with the Patent's Disclosure

In finding a likelihood of infringement, the district court relied on the declaration of Covidien's expert Dr. Durfee, in which he described tests with pig tissue and paper that purportedly show that the ACE+7 infringes claim 15. A0009-A0010. As shown in the illustration reproduced below, the tissue stops on the ACE+7's outer tube, which extend distally past the sides of the clamp directly adjacent to the cutting surface, are obscured from view by the pig tissue in Dr. Durfee's tests. Instead, Dr. Durfee identified the side of the clamp as the "tissue engaging stop." Dr. Durfee also identified what he considered to be "the proximal end of the cutting surface"; he located it at the *back* (proximal) side of the clamp, well removed from what he considered to be the "tissue engaging stop." *See* A1171 (labels in original).



Dr. Durfee thus applied a claim construction and scope that treats "the proximal end of the cutting surface" as separate from, and significantly proximal to, the "tissue engaging stop." Based on this claim scope, Dr. Durfee opined that the sides of the ACE+7's clamp meet the limitations of claim 15 because they engage tissue before it reaches "the proximal end of the cutting surface." Under Dr. Durfee's construction, the fact that the tissue stops on the outer tube of the ACE+7 are distal to (closer to the end of the blade than) the sides of the clamp is irrelevant to the infringement analysis; it simply means that the ACE+7 has multiple tissue stops, not that Ethicon designed around the claim. A1167/¶46; A1169/¶51.

But as Ethicon demonstrated, the specification of the '286 patent makes clear that "the proximal end of the cutting surface" is defined by the

location of the tissue stops, which on the ACE+7 device are on the outer tube. The specification is explicit on this subject. With respect to the sole embodiment of the invention described in the patent, *see* A0054/col. 2:15-62, it states that "[c]lamp body 62 includes a pair of tissue receiving stops 71" and that these tissue receiving stops "*define the proximal end of the exposed blade surface 59*." A0055/col.3:67-col.4:1 (emphasis added).[8]

Under a construction that is consistent with the specification, "the proximal end of the cutting surface" in the ACE+7 device is defined by the outer tube tissue stops, which mark the end of the exposed blade surface. Because the cutting surface of claim 15 can only have one "proximal end" – to use the words of the claim, "*the* proximal end" – the sides of the clamp, which are located further back on the instrument, do not prevent tissue from moving beyond the proximal end of the cutting surface, as claim 15 requires.

In rejecting Ethicon's non-infringement defense, the district court made multiple errors of law. First, the district court erred by refusing to construe a disputed claim term. The court "disagree[d]" with Ethicon's contention that a "full claim construction inquiry" of the term "proximal end of the cutting surface" was

[8] As noted above, both sides agree that "tissue engaging stops" (in claim 7) and "tissue receiving stops" (*e.g.*, at A0056/col.5:56-58) have the same meaning, as do the terms "cutting surface" (in claim 7) and "exposed blade surface" (*e.g.*, at A0055/col.3:67–4:1).

required, instead stating that the prior court's construction of different claim terms such as "tissue engaging stops" and "blade surface" "sufficiently resolves the meaning of claim 15 of the '286 patent." A0008.[9] This was incorrect. As discussed above, the prior court's claim constructions did not resolve whether "the proximal end of cutting surface" is defined by the location of the tissue stops, as the specification states, or whether it is located somewhere else, as Covidien's expert opined. The court's refusal to resolve the parties' dispute over the proper meaning of this term was error. *See O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co*., 521 F.3d 1351, 1361 (Fed. Cir. 2008) (district court's "determination that a claim term 'needs no construction'" was error because the parties disputed the "scope of the asserted claims").

Second, the district court erred by failing to give any weight to the specification's clear teaching about the location of "the proximal end of the cutting surface." The district court concluded that this teaching was not controlling because it "describ[ed] a physical boundary" in a particular embodiment rather than providing a lexicographical definition of a word. A0011-A0012. But the distinction between a lexicographical definition and a physical one is irrelevant

[9] As the district court noted, the *Tyco* court construed "tissue engaging stops" to mean "the portions of the clamp that engage tissue and prevent tissue from moving past the proximal portion end of the blade surface" and "blade surface" to mean "the face that engages tissue to achieve cutting." A0008.

here. The question of lexicography arises when a party wishes to invoke the lexicographer "exception" to the general rule that claims are "given their ordinary and customary meaning as understood by a person of ordinary skill in the art *when read in the context of the specification and prosecution history*." *Thorner v. Sony Computer Entm't Am. LLC*, 669 F. 3d 1362, 1365-66 (Fed. Cir. 2012) (emphasis added). Here, Ethicon does not need to invoke the "lexicographer" exception, because its proposed construction is the ordinary and customary meaning of the term read in the context of the specification. The patent teaches that the "end" of the cutting surface is where cutting is obstructed, i.e., at the tissue stops. There is nothing non-customary or extraordinary about this usage.

In contrast, the claim scope and construction that Dr. Durfee applied places the proximal end of the cutting surface in a different location than the tissue stops. This is contrary to the intrinsic record and therefore "improper." *Power Integrations v. Fairchild Semiconducto*r, 711 F. 3d 1348, 1362 (Fed. Cir. 2013) ("Unless the inventor intended a term to cover more than the ordinary and customary meaning *revealed by the context of the intrinsic record*, it is improper to read the term to encompass a broader definition simply because it may be found in a dictionary, treatise, or other extrinsic source.") (emphasis in original). The district court erred by relying on an expert declaration that is premised on an incorrect claim scope and construction. *See, e.g.*, *Cordis Corp. v. Boston Scientific*

Corp., 658 F.3d 1347, 1357 (Fed. Cir. 2011) ("[W]e must disregard the testimony of [an] expert" that "was based on an incorrect understanding of the claim construction.").

Finally, the district court compounded its error by reasoning that even if tissue engaging stops define the proximal end of the cutting surface under the meaning of claim 15, the tissue stops on the outer tube of the ACE+7 cannot fulfill that function because, despite defining the location at which tissue moving along the cutting surface will be stopped, they "do not stop all the tissue" and "are not on the clamp body." A0012-A0013. But the patent does not require that the tissue stops defining the proximal end of the cutting surface "stop all the tissue." On the contrary, the sole embodiment described in the specification has a "pair of tissue receiving stops" on either side of the cutting surface through which tissue might be capable of being forced, just as in the ACE+7.[10] A0055/col.3:67; *see also* A0045 (Fig. 9).

As for the district court's suggestion that the tissue stops on the outer tube of the ACE+7 cannot define the proximal end of the cutting surface because they are "not on the clamp" as the specification teaches, this is entirely circular.

[10] Furthermore, as discussed below, tissue forced between the tissue stops on the cutting surface of the ACE+7 would not be stopped by the clamp, as the district court assumed, because the clamp is located outside the tissue stops, not between them. *See* A1446/¶59.

A0012. Of course the patent teaches that the tissue stops defining the proximal end of the cutting surface are on the clamp; that is what claim 15 recites. The theory of Ethicon's design around was to place these tissue stops on the outer tube in order to avoid infringement. In rejecting this design around because the ACE+7's outer tube tissue stops are "not on the clamp," the district court effectively held that claim 15 should not be construed or applied in a way that would lead to a finding of non-infringement in this case. This was improper. *See Sri Int'l v. Matsushita Elec. Corp. of Am.*, 775 F. 2d 1107, 1118 (Fed. Cir. 1985) (en banc) ("[C]laims are not construed 'to cover' or 'not to cover' the accused device.").

2. The District Court Erred in Finding That the Clamp of the ACE+7 Functions as a Tissue Stop

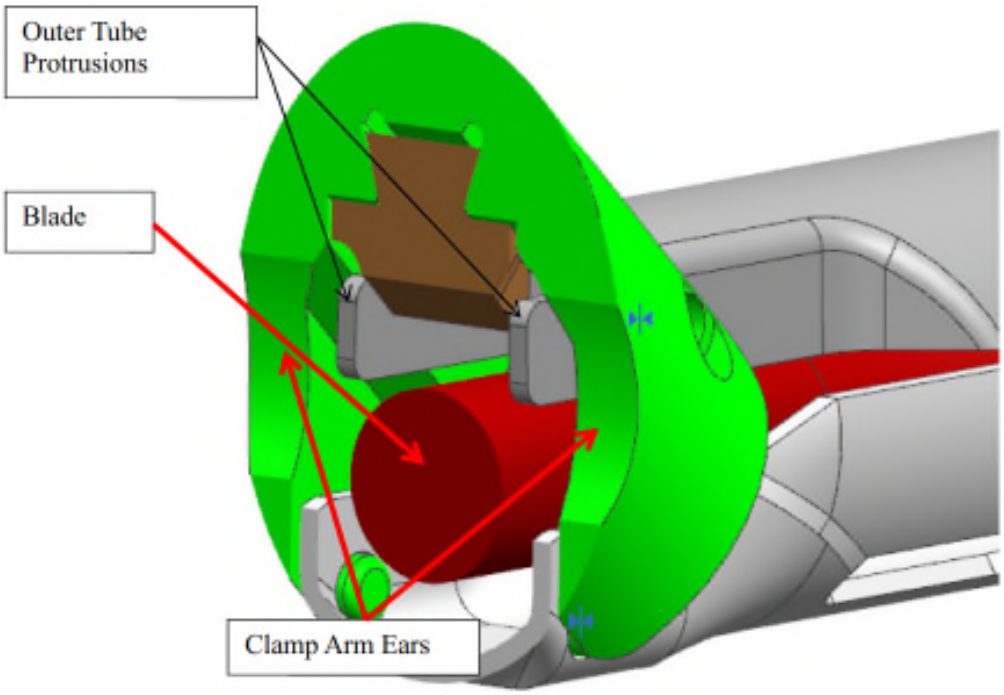
Regardless of where "the proximal end of the cutting surface" is placed, the district court erred in finding that Covidien had made a "clear showing" of infringement. *Sussman v. Crawford*, 488 F. 3d 136, 139 (2d Cir. 2007) (quoting *Mazurek*, 520 U.S. at 972). At a preliminary stage and on a paper record, without expert discovery or cross-examination, the evidence was simply insufficient for the court to resolve the dispute between the parties' experts in Covidien's favor on whether the sides of the ACE+7's clamp function as tissue stops.

As noted above, the court accepted the "observ[ation]" of Covidien's expert Dr. Durfee that the ACE+7 infringed claim 15. A0009-A0010. According to Dr. Durfee's declaration, his chamois and pig-tissue tests showed contact with

the sides of the clamp during cutting. Therefore, he argued that the clamp prevented tissue from moving past what he considered to be the proximal end of the cutting surface and met the limitations of the claim. A1169-A1171/¶¶49-54.

But as Ethicon's Dr. Cimino pointed out, Dr. Durfee's experiments could not permit anyone to "observe" infringement, because, as the photograph reproduced above illustrates, the tissue in Dr. Durfee's experiments completely covers the tissue stops on the ACE+7's outer tube, making it impossible to conclude that it is the clamp, rather than the outer tube, that prevents movement of tissue on the blade's cutting surface. A1446-A1447/¶¶60-62. All Dr. Durfee's tests show is that the "clamp . . . may impede tissue from moving proximally along the *sides* of the blade" – not its cutting surface. A1446/¶59.

Dr. Cimino explained that it is the outer tube, and not the clamp, that stops tissue from moving along the *cutting surface* of the ACE+7. Notably, as Dr. Cimino pointed out, this is true not only in the area where the outer tube extends distally beyond the sides of the clamp, but all the way up the blade, where the two sides of the outer tube act as walls shielding the blade's cutting surface from the sides of the clamp. A1445-A1446/¶¶57-59 & Fig. H (see below).



As Dr. Cimino explained, "even if tissue is somehow forced beyond the distal edge of the outer tube," the outer tube "will continue to be the structure that prevents tissue from moving proximally along the *blade surface* …." A1446/¶59.

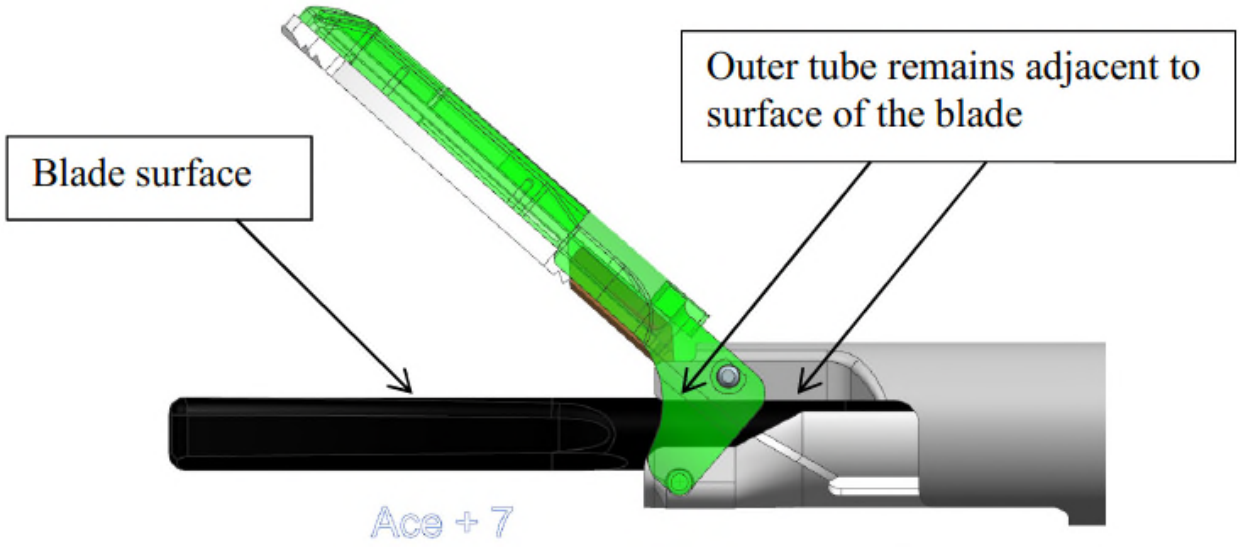
In rejecting Dr. Cimino's analysis, the district court first questioned whether claim 15 requires tissue stops to prevent tissue from moving "along" the cutting surface. A0013-A0014. The term "along" was used by Dr. Durfee in *Tyco* and by the *Tyco* court in applying the "tissue engaging stop" element of claim 15. A1802-A1803. As they recognized, in order for a tissue stop to prevent tissue from moving "beyond the proximal end of the cutting surface" as claim 15 requires, it must prevent tissue from moving along the cutting surface in a proximal direction. In any event, Dr. Cimino's opinion was that the ACE+7 does

not meet the limitations of claim 15 because its clamp does not prevent tissue from moving beyond the proximal end of the cutting surface. A1447/¶63. This opinion does not rely on the word "along."

The district court then found that contrary to Dr. Cimino's opinion, the ACE+7's clamp does stop tissue along the cutting surface. A0014. In reaching this conclusion, the district court did not rely on Dr. Durfee's tissue tests – which as noted shed no light on what occurs on the cutting surface – but rather on the paper tests in Dr. Durfee's reply declaration, in which he claimed to have thrust a piece of paper underneath the tissue stops on the ACE+7's outer tube and into contact with the clamp. Based on this declaration, the court concluded that there are "gaps between the outer tube protrusions and the blade surface" that would allow tissue to "squeeze through the gaps between the outer tube protrusions, slide along the blade, and ultimately press against the clamp ears." A0014.

The court made no attempt to explain why it was crediting Dr. Durfee's reply declaration over the opinion of Dr. Cimino, who not only disagreed that tissue forced past the edge of the tissue stops in the ACE+7's outer tube would be stopped by the clamp, A1446/¶59, but also presented a paper test of his own showing that paper would *not* slip underneath the outer tube tissue stops, A1441. Without the benefit of expert discovery, depositions, or cross-examination, there was no basis for the court to make such a credibility finding.

Engineering drawings submitted by Ethicon, like the drawing reproduced below (A1446 Fig. I), refute Dr. Durfee's assertion that there is a vertical gap between the tissue stops on the ACE+7's outer tube and the cutting surface of the blade through which anything can be slipped.



In his paper test, Dr. Durfee apparently angled the paper under the tissue stops on the side of the blade, rather than on the blade's *cutting surface* as claim 15 requires. A1653-A1656/¶¶7-10.[11] No evidence supports the district court's conclusion that tissue could "squeeze" beneath the tissue stops on the ACE+7's outer tube in this fashion. Neither Dr. Durfee nor anyone else has suggested that human tissue would behave like the paper in Dr. Durfee's test. *Id.*

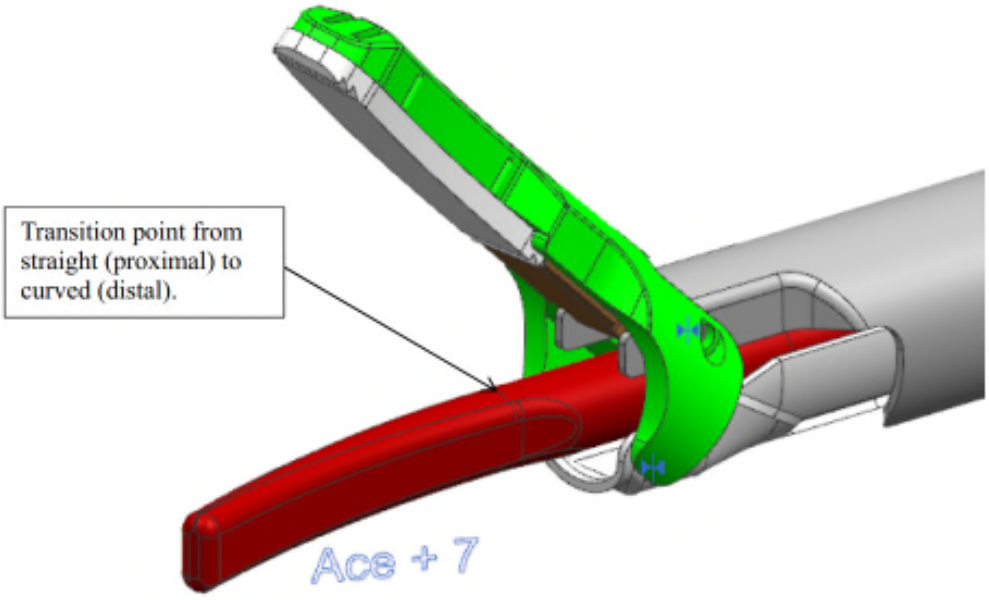
[11] Dr. Durfee had also "disassembled" his ACE+7 device. A1169/¶48. Without discovery, it is unknown whether he reassembled the components as tightly as they are configured in commercial devices.

In sum, the district court lacked a sufficient basis in the record to resolve what it acknowledged was a "fierce[]" dispute between Dr. Durfee and Dr. Cimino in Dr. Durfee's favor. A0008. *See, e.g.*, *Davis v. N.Y.C. Hous. Auth.*, 166 F. 3d 432, 437-38 (2d Cir. 1999) ("[W]hile affidavits may be considered on a preliminary injunction motion, motions for preliminary injunction should not be resolved on the basis of affidavits that evince disputed issues of fact.") (citing *Forts v. Ward*, 566 F.2d 849, 851 (2d Cir.1977)). As a result, the injunction must be vacated. *See Vascular Solutions, Inc. v. Boston Sci. Corp.*, 562 F. App'x 967 (Fed. Cir. 2014) (vacating preliminary injunction where "there are too many unresolved issues at this stage of the case and the record is too incomplete on issues of claim construction, infringement, and ultimate validity to warrant the grant of a preliminary injunction").

3. The District Court Erred in Ruling that Claim Preclusion Bars Ethicon from Asserting that the Tissue Engaging Stops Must Be on the Curved Surface of the Cutting Jaw

Finally, the district court erred in holding that claim preclusion bars Ethicon from asserting that the ACE+7 device does not infringe based on the curvature of its blade. Claim 7, from which claim 15 depends, requires the "tissue engaging stop" on the "clamp arm" to "prevent positioning of tissue beyond the proximal end of the cutting surface of the cutting jaw." Claim 15 adds the requirement that the "cutting surface of the cutting jaw" is "curved." Thus, to

infringe claim 15, a tissue stop on the clamp arm must prevent movement of tissue beyond the proximal end of the *curved* cutting surface. This does not happen in the ACE+7 device because it was undisputed that the curved portion of the blade ends well before the clamp. A1447-A1449/¶¶64-67 (see below).



In holding that Ethicon could not raise this issue because of claim preclusion, A0015-A0016, the district court made the same error that this Court addressed in its seminal claim preclusion decision, *Foster v. Hallco Mfg. Co., Inc.*, 947 F. 2d 469 (Fed. Cir. 1991). In that case, this Court explained that in the claim preclusion context, "'claim' does not mean merely 'argument' or 'assertion'" but rather "the facts giving rise to the suit." *Id.* at 478. Thus, the Court concluded, "claim preclusion applies in this case only if [the] infringement claim rests on the same transactional facts" as in the previous action. *Id.* at 479.

Here, the district court below expressly found that "the devices at issue before the court in the *Tyco* litigation were different from the ACE+7." A0017. This was not surprising, as it was undisputed that Ethicon had redesigned its device since the previous trial for the precise purpose of avoiding the "tissue engaging stop" limitation of claim 15. *See Del Mar Avionics, Inc., v. Quinton Instrument Co.*, 836 F.2d 1320, 1324 (Fed. Cir. 1987) (noting that a "device not previously before the court, and shown to differ from those structures previously litigated, requires determination on its own facts"). In finding claim preclusion applicable to one of Ethicon's non-infringement arguments, the court was incorrectly treating a "claim" as an "argument or assertion," rather than as the "facts giving rise to the suit." *Foster*, 947 F. 2d at 478.[12]

The district court also stated that although the blade of the ACE+7 is straight at the point where it meets the clamp, "the blade as a whole is clearly curved." A0016. But claim 15 requires a curved "cutting surface," and when read along with the language of claim 7, it requires that the tissue stop prevent tissue from moving beyond the proximal end of the curved cutting surface. The district court's observation that the ACE+7's "blade as a whole" is curved is irrelevant, because it is undisputed that the *cutting surface* of the ACE+7 is not curved at the

[12] As in *Foster*, the reason the court relied on claim preclusion, rather than issue preclusion, was likely that issue preclusion is limited "to issues actually litigated," which is not the case here. *Foster*, 947 F. 2d at 478.

location where it meets the clamp. If the ACE+7's clamp stops tissue from moving past any portion of the cutting surface – and it does not, for the reasons discussed above – that cutting surface is straight, not curved. For this reason as well, the ACE+7 does not infringe claim 15.

POINT II

THE DISTRICT COURT ERRED IN FINDING THAT COVIDIEN WOULD BE IRREPARABLY HARMED

The district court also erred in finding that Covidien had met its burden of showing irreparable injury that could not be remedied by money damages. That error provides a separate and independent basis for reversing the preliminary injunction.

After a full trial, the *Tyco* court concluded that Tyco was not entitled to lost profits damages because its RF devices are so different from Ethicon's ultrasonic instruments that Ethicon's sales of curved blade ultrasonic instruments would not cause Tyco to lose any sales or profits. *Tyco*, 936 F. Supp. 2d at 78 (discussing the "recognized cutting deficiencies" of RF devices). It found that any harm to Tyco/Covidien from Ethicon's sale of such instruments is not irreparable and that "'remedies available at law, such a[s] monetary damages,' are fully adequate to compensate for Tyco's injury." *Id.* at 86.

With the *Tyco* court having rejected Tyco/Covidien's claim that it is irreparably harmed by Ethicon's sale of curved blade ultrasonic instruments, the district court should not have permitted Covidien to re-litigate that issue here.

Under applicable Second Circuit law, the *Tyco* court's findings on irreparable harm deserved collateral estoppel effect.[13]

In the Second Circuit, "collateral estoppel applies when: (1) the issues in both proceedings are identical, (2) the issue in the prior proceeding was actually litigated and actually decided, (3) there was full and fair opportunity to litigate in the prior proceeding, and (4) the issue previously litigated was necessary to support a valid and final judgment on the merits." *Ali v. Mukasey*, 529 F.3d 478, 489 (2d Cir. 2008); *see also Carney v. Phillipone*, 332 F.3d 163, 169-70 (2d Cir. 2003) (same). All four factors are met here: (1) this case and the *Tyco* case both involved Tyco/Covidien's assertion that it would be irreparably harmed by Ethicon's sale of ultrasonic instruments with a curved blade that practice claim 15; (2) that issue was actually litigated and decided in *Tyco*; (3) Tyco/Covidien had a full and fair opportunity to litigate in *Tyco*; and (4) the *Tyco* court's determination on the issue was necessary to support its final judgment that Tyco/Covidien was not entitled to injunctive relief. *See Tyco*, 936 F. Supp. 2d at 86.

The district court's error in allowing Covidien to re-litigate the issue is illustrated by its acceptance of an assertion, by Covidien's Director of Global Marketing, that sales of the ACE+7 would "falsely give[ ] consumers the

[13] *See Transocean Offshore Deepwater, Inc. v. Maersk Contractors USA, Inc.*, 617 F.3d 1296, 1311 (Fed. Cir. 2010) (This Court "analyze[s] collateral estoppel under the law of the regional circuit.").

impression that Ethicon was the innovator [of ultrasonic devices with a curved blade]." A0020-A0021. The devices in *Tyco* also were ultrasonic instruments with a curved blade, and those devices were found not to cause irreparable harm to Covidien. *Tyco*, 936 F. Supp. 2d at 86. Covidien should not have been allowed to re-litigate the issue here.

In rejecting the applicability of collateral estoppel on irreparable harm, the district court stated that the ACE+7 is unlike the devices in *Tyco* because it "allows surgeons to seal vessels up to seven millimeters in size" and this "increases the potential harm to Covidien …." A0017. At most, the fact that ACE+7 can seal vessels up to 7 mm in size means that it may better compete against Covidien's RF instruments in a broader range of sizes. It does not transform injury that is compensable by money damages into irreparable injury.

Moreover, the ability to seal vessels of a particular size is not a "patented feature" of claim 15. *Apple Inc. v. Samsung Elecs. Co.*, 678 F.3d 1314, 1324 (Fed. Cir. 2012) ("*Apple I*"). As such it cannot provide the requisite "causal nexus [that] relates the alleged harm to the alleged infringement" and is not "pertinent to the injunctive relief analysis." *Apple, Inc. v. Samsung Elecs, Co.*, 695 F.3d 1370, 1374 (Fed. Cir. 2012) ("*Apple II*"). "Sales lost to an infringing product cannot irreparably harm a patentee if consumers buy that product for reasons other

than the patented feature." *Apple I*, 678 F.3d at 1324; *see also Apple, Inc. v. Samsung Elecs. Co.*, 735 F.3d 1352, 1365 (Fed. Cir. 2013) ("*Apple III*").

Demand for the ACE+7 over the devices in issue in *Tyco* is not driven by any feature that claim 15 requires. *See supra* p. 28. Covidien did not dispute this. The only commercially significant difference between the two is the new algorithm that allows better precision and the ability to treat larger vessels.

The district court concluded that the ACE+7's curved blade provides the requisite nexus between the patent and Covidien's claimed injury. A0021-A0022. But the devices in *Tyco* also had a curved blade and the *Tyco* court found that "'remedies available at law, such a[s] monetary damages,' are fully adequate to compensate" Tyco/Covidien for Ethicon's sale of such devices. 936 F. Supp. 2d at 86.

The district court did not point to – and Covidien cannot identify – any difference between the ACE+7 and the devices at issue in *Tyco* that could support a different result. For purposes of this appeal, the ACE+7 differs from the devices in *Tyco* in only two respects: (1) it uses an improved algorithm that provides better precision and enables the device to cut and seal larger vessels, up to 7 mm; and (2) its tissue engaging stops are part of the outer tube. *See supra* pp. 12-14. Claim 15 does not mention or require either feature. Neither is a "patented feature" of the claim, *Apple I*, 678 F.3d at 1324, and neither can provide the

requisite "connection between the patented feature and demand for [the accused] products." *Apple III*, 735 F.3d at 1364. In the absence of any such nexus, Covidien lacked sufficient grounds for asserting irreparable harm. It was attempting "to leverage its patent for competitive gain beyond that which the inventive contribution and value of the patent warrant." *Apple II*, 695 F.3d at 1375.

In addition, the district court's reliance on harm to Covidien's good will and reputation is misplaced for two other reasons. First, Ethicon has every right to promote itself as the innovator of ultrasonic instruments with a curved blade. After all, Ethicon owns the Davison '055 patent, which discloses an ultrasonic instrument with that feature and is prior art for the '286 patent-in-suit. *Tyco*, 936 F. Supp. 2d at 49. Second, Covidien's reputation in the advanced energy field stems from its dominance in the sale of RF instruments, not from sales of ultrasonic devices. A0635-A0637/¶¶9-24.

Finally, the alleged economic harm to Covidien is minimal. Covidien has [redacted] in annual sales from its LigaSure RF devices – and that is only [redacted] of its total business. A0636/¶14. The ACE+7 is projected to take [redacted] sales away from non-Ethicon instruments (whether ultrasonic or RF). A1828-A1829. Thus, the ACE+7 is no threat to Covidien's continuing as a "giant[]" in this surgical device field. *Tyco*, 936 F. Supp. 2d at 86.

Accordingly, here, as in *Tyco*, money damages are "fully adequate" to compensate Covidien for its alleged injuries. *Id*.

POINT III

CONSIDERING THE EQUITIES, THE DISTRICT COURT ABUSED ITS DISCRETION IN GRANTING A PRELIMINARY INJUNCTION AGAINST AN IMPORTANT SURGICAL DEVICE

A preliminary injunction "is an extraordinary and drastic remedy, one that should not be granted unless the movant, by a clear showing, carries the burden of persuasion." *Mazurek*, 520 U.S. at 972; *see also LifeScan*, 734 F.3d at 1366 (same); *Moore*, 409 F.3d at 510 (Sotomayor, J.) (same).

The district court committed a clear error in judgment, and abused its discretion, by granting this remedy here. The preliminary injunction deprives doctors and patients of an important surgical instrument, one that many doctors consider to be the best choice for certain complex procedures. There is "strong public interest" in giving surgeons a broad choice of such devices. *Cordis*, 99 F. App'x at 935 ("a strong public interest supports a broad choice of drug eluting stents, even though no published study proves the superiority of either [side's] stent."); *see also Datascope*, 786 F.2d at 401 ("the public [would] be harmed by an injunction" against a medical device that some physicians prefer). The district court failed to give appropriate weight to that strong public interest.

Ordering an injunction against the ACE+7 was particularly unwarranted when Covidien does not make or sell any ultrasonic device with a curved blade. A0023-A0024; A0822 n.15. The '286 patent describes the

advantages of using an ultrasonic instrument with a curved blade. The injunction will deprive doctors and patients of those advantages. Neither Covidien nor anyone else sells an ultrasonic device that provides the benefits of the ACE+7. A1501-A1502/¶¶22-23; A1583/¶19; A1926/¶9; A1929/¶21; A1933-A1934/¶5-8. As the court in the *Tyco* case found, money damages could "adequately" and "fully" compensate Covidien for any harm that results from Ethicon's sale of ultrasonic instruments with a curved blade. *Tyco*, 936 F. Supp. 2d at 86.

The district court's effort to weigh the equities also misses the mark in other respects. Contrary to the court's findings, the harm to Ethicon from having to discontinue its sales of the ACE+7 far outweighs any harm to Covidien from having to compete in the marketplace against the ACE+7. Hospitals and doctors rely on Ethicon to provide safe, reliable surgical devices and to be able to continue supplying those medical devices. A1501-A1502/¶23; A1924-A1925/¶¶3-4; A1929/¶20. An injunction against the ACE+7 severely damages the trust and goodwill that Ethicon has worked hard to earn.

Last but not least, the district court should have factored in the possibility that the validity decision in *Tyco* might be reversed on appeal. Instead, it gave the *Tyco* decision preclusive effect and left it to this Court to decide whether "there are substantial questions as to the validity of claim 15 of the '286 patent …." A0034.

Weighing all of the equities, the district court made a clear error of judgment and abused its discretion in granting the preliminary injunction.

CONCLUSION

This Court should reverse the grant of a preliminary injunction.

Dated: November 17, 2014

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CERTIFICATE OF SERVICE

I hereby certify that on November 17, 2014, I caused the foregoing **CORRECTED BRIEF FOR DEFENDANT-APPELLANT** to be electronically filed with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to the registered attorney(s) of record that the document has been filed and is available for viewing and downloading.

In addition, a copy of the brief will be sent via electronic mail on the same date as above to:

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November 17, 2014

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of FED. R. APP. P. 32(a)(7)(B). The brief contains 13,877 words, as calculated by the word count of the word processing system used in preparing it, excluding the parts of the brief exempted by FED. R. APP. P. 32(a)(7)(B)(iii) and FED. CIR. R. 32(b).

This brief complies with the typeface requirements of FED. R. APP. P. 32(a)(5) and the type style requirements of FED. R. APP. P. 32(a)(6). The brief has been prepared in Microsoft Word 2010 in Times New Roman 14 point font.

November 17, 2014

/s/ William F. Cavanaugh, Jr.
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ADDENDUM

UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

COVIDIEN SALES LLC and COVIDIEN LP, Plaintiffs,	:	CIVIL ACTION NO. 3:14-cv-917 (JCH)
v.	:	
ETHICON ENDO-SURGERY, INC., Defendant.	:	OCTOBER 15, 2014

RULING [REDACTED] RE: MOTION FOR PRELIMINARY INJUNCTION (Doc. No. 45)

I. INTRODUCTION

Plaintiffs Covidien Sales LLC and Covidien LP ("Covidien," collectively) brought this patent infringement action against defendant Ethicon Endo-Surgery, Inc. ("Ethicon"), alleging that Ethicon sells products that infringe a number of Covidien's patents, including U.S. Patent No. 6,468,286, entitled "Ultrasonic Curved Blade" (the " '286 patent"). Covidien filed a Motion for Preliminary Injunction (Doc. No. 45), seeking to enjoin Ethicon's production, sale, and use of one product in particular, the Harmonic ACE+7 Shears (the "ACE+7"), based on its alleged infringement of the '286 patent.

For the following reasons, the court grants Covidien's Motion for Preliminary Injunction.

II. BACKGROUND

This Motion for Preliminary Injunction is the latest battle in what appears to be a lengthy patent war between Covidien and Ethicon. For the sake of brevity, the court sets forth only the essential background facts. Covidien and Ethicon are the largest manufacturers of laparoscopic advanced energy surgical devices, and they compete

fiercely. In October 2004, Covidien, who was then known as the Tyco Healthcare Group LP, and Ethicon began litigating infringement and validity issues surrounding a set of patents, of which the '286 patent is a member, related to these advanced energy surgical devices. This court (Judge Janet B. Arterton) previously resolved a number of claim construction, validity, infringement, and damages issues. See Tyco Healthcare Grp. LP v. Ethicon Endo-Surgery, Inc. (Tyco I), 411 F. Supp. 2d 93 (D. Conn. 2006); Tyco Healthcare Grp. LP v. Ethicon Endo-Surgery, Inc. (Tyco II), 440 F. Supp. 2d 120 (D. Conn. 2006); Tyco Healthcare Grp. LP v. Ethicon Endo-Surgery, Inc. (Tyco III), 514 F. Supp. 2d 351 (D. Conn. 2006); Tyco Healthcare Grp. LP v. Ethicon Endo-Surgery, Inc. (Tyco IV), 936 F. Supp. 2d 30 (D. Conn. 2006). The court refers to these opinions and their related proceedings as the "Tyco litigation." The Tyco litigation continues today in the form of an appeal, which is currently pending. See Notice of Appeal, Tyco Healthcare Grp. LP v. Ethicon Endo-Surgery, Inc., No. 3:10-CV-60, ECF No. 232 (JBA) (D. Conn. Apr. 5 2013).

The only part of the Tyco litigation directly relevant here is Judge Arterton's ruling that claim 15 of Covidien's '286 patent was valid and infringed by Ethicon and the ruling's related claim construction. See Tyco III, 514 F. Supp. 2d at 374–75; Tyco IV, 936 F. Supp. 2d at 71. Ethicon has appealed that validity ruling on claim 15, among other things, to the Federal Circuit. See Pls.' Mem. Supp. 6 (Doc. No. 46). After finding that certain Ethicon products infringed claim 15 of the '286 patent, Judge Arterton awarded Covidien reasonable royalties and prejudgment interest, but she denied Covidien's requests for a permanent injunction and lost profits. Tyco IV, 936 F. Supp. 2d at 71–87.

Covidien's instant Motion for Preliminary Injunction seeks to enjoin Ethicon's production, sale, and use of the ACE+7. The ACE+7 is Ethicon's attempt to design around the teachings of claim 15 of the '286 patent, as construed in the Tyco litigation. Def.'s Mem. Opp'n 7–10 (Doc. No. 53). Specifically, Ethicon claims that the ACE+7 avoids infringement by virtue of its modified clamp ears, its outer tube protrusions, and the fact that a portion of the blade is straight distal to the clamp ears.

III. STANDARD OF REVIEW

Federal Circuit law applies to issues of patent law, and Second Circuit law applies to all other issues. See In re Cambridge Biotech Corp., 186 F.3d 1356, 1368 (Fed. Cir. 1999). "[A] preliminary injunction enjoining patent infringement . . . involves substantive matters unique to patent law and, therefore, is governed by the law of [the Federal Circuit]." Revision Military, Inc. v. Balboa Mfg. Co., 700 F.3d 524, 525 (Fed. Cir. 2012) (internal quotation marks omitted).

A preliminary injunction is an "extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief." Winter v. Natural Res. Def. Council, Inc., 555 U.S. 7, 22 (2008). A "plaintiff seeking a preliminary injunction must establish [1] that he is likely to succeed on the merits, [2] that he is likely to suffer irreparable harm in the absence of preliminary relief, [3] that the balance of equities tips in his favor, and [4] that an injunction is in the public interest." Titan Tire Corp. v. Case New Holland, Inc., 566 F.3d 1372, 1375 (Fed. Cir. 2009) (quoting Winter, 555 U.S. at 20).

IV. DISCUSSION

The parties dispute each of the preliminary injunction factors.

First, Covidien argues that Ethicon is precluded from challenging the validity and infringement conclusions in the Tyco litigation, and that its instant patent infringement suit is likely to succeed on the merits, even if Ethicon is not precluded. Second, Covidien argues that Ethicon's infringement of claim 15 of the '286 patent will cause irreparable harm in the forms of lost market share, business opportunities, reputation, and goodwill. Third, Covidien argues that the balance of the equities tip in its favor because Ethicon is willfully infringing and advertising Covidien's patented features in its marketing campaigns, and because it could have easily avoided infringement. Fourth, Covidien argues that a preliminary injunction is in the public interest because it is necessary to foster respect for the law and the patent system, and because Ethicon's infringement blatantly disregards those values.

Ethicon disputes all of Covidien's arguments. The court addresses each factor in turn.

A. Likelihood of Success on the Merits

For a patentee to establish that it is likely to succeed on the merits, it must show that it is likely to prove infringement of its patent claim and that the infringed-upon claim is valid. See AstraZeneca LP v. Apotex, Inc., 633 F.3d 1042, 1050 (Fed. Cir. 2010). "A preliminary injunction should not issue if an alleged infringer raises a substantial question regarding either infringement or validity . . . ." Id. To determine whether a claim has been infringed, the court engages in a two-step analysis: "First, the claim must be properly construed to determine its scope and meaning. Second, the claim as properly construed must be compared to the accused device or process." Carroll Touch, Inc. v. Electro Mech. Sys., Inc., 15 F.3d 1573, 1576 (Fed. Cir. 1993).

1. Validity of Claim 15 of the ’286 Patent

Covidien argues that issue preclusion bars Ethicon from disputing the validity of the ’286 patent, based on the results of the Tyco litigation. Pls.’ Mem. Supp. 23. Issue preclusion, also known as collateral estoppel, applies only if: “(1) the issue is identical to one decided in the first action; (2) the issue was actually litigated in the first action; (3) resolution of the issue was essential to a final judgment in the first action; and (4) the party against whom estoppel is invoked had a full and fair opportunity to litigate the issue in the first action.” Innovad Inc. v. Microsoft Corp., 260 F.3d 1326, 1334 (Fed. Cir. 2001).

The second, third, and fourth elements are satisfied, because the validity of claim 15 of the ’286 patent was actually, fully, and fairly litigated by Ethicon in the prior litigation, and resolution of the issue was essential to a final judgment. See Tyco VI, 936 F. Supp. 2d at 65–68. The first element – whether the issues are identical – is also met because “[t]he relevant ‘issue’ which [a party is] precluded from relitigating is the ultimate determination on patent validity itself.” Roche Palo Alto LLC v. Apotex, Inc., 526 F. Supp. 2d 985, 994–95 (N.D. Cal. 2007), aff'd, 531 F.3d 1372 (Fed. Cir. 2008). In other words, once a patent is deemed valid, the party who previously challenged its validity cannot do so again with new arguments. See id. at 995 & n.3.

Given that claim 15 of the ’286 patent was ruled valid in the Tyco litigation, see Tyco IV, 936 F. Supp. at 67–68, Ethicon concedes that issue preclusion bars it from re-challenging validity. See Def.’s Mem. Opp’n 24; Oral Argument Tr. 67. Ethicon is precluded from challenging claim 15’s validity because a district court’s judgment is final for the purpose of issue preclusion. See Conopco, Inc. v. Roll Int'l, 231 F.3d 82, 90 (2d

Cir. 2000) ("It is true that (in stark contrast to the rules in federal court and the vast majority of states) California does indeed require that a judgment be both final *and non-appealable* (*i.e.,* the appellate process has concluded or the time in which to appeal has passed) before it will earn *res judicata* or *collateral estoppel* effect." (emphasis in original)).

2. Construction of Claim 15 of the '286 Patent

Two of the '286 patent's claims are relevant to this Motion: dependent claim 15, and independent claim 7, on which claim 15 depends.

Claim 7 teaches:

An ultrasonic instrument comprising:

a) a handle assembly;

b) a vibration coupler supported by and extending distally from the handle assembly;

c) a cutting jaw having a cutting surface operatively connected to the vibration coupler;

d) a clamp member supported adjacent to the cutting jaw, the clamp member and the cutting jaw defining a tissue receiving area, the clamp member being moveable between open and closed positions in relation to the cutting jaw and having a tissue engaging stop positioned to engage tissue and prevent positioning of tissue beyond the proximal end of the cutting surface of the cutting jaw.

'286 Patent.

Claim 15 teaches: "An ultrasonic instrument according to claim 7, wherein the cutting surface of the cutting jaw is curved along the longitudinal axis of the instrument." '286 Patent.

The parties have no dispute regarding parts (a) through (c) of claim 7; the disagreements involve only claim 15 and part (d) of claim 7.

In addition to the language of the claims, the court has the benefit of Judge Arterton's claim construction from the Tyco litigation. "Claim construction is a question of law that may require determination of underlying facts. To the extent that the underlying facts are based on identical premises, . . . the prior findings and the claim construction based thereon are the law of the case. They are not available for redetermination." Del Mar Avionics, Inc. v. Quinton Instrument Co., 836 F.2d 1320, 1324 (Fed. Cir. 1987) (internal citation omitted).

Neither party seems to dispute Judge Arterton's claim construction;[1] instead, each disputes how her construction bears on the alleged infringement in this case. See Pls.' Reply 2; Def.'s Mem. Opp'n 7; Oral Argument Tr. 29, 55. The court adopts Judge Arterton's claim construction to the extent it is relevant here.

Judge Arterton construed the terms "curved along the longitudinal axis," "clamp member," "tissue engaging stops," and "blade surface." The first of these terms appears in claim 15, while the second, third, and fourth appear in claim 7. Judge Arterton construed:

(1) "curved along the longitudinal axis" to mean "deviating from a straight line along the lengthwise dimension." Tyco I, 411 F. Supp. 2d at 107. She also clarified that this construction "should not be read to limit that curvature to surfaces curving only up or down." Tyco II, 440 F. Supp. 2d at 123;

(2) "clamp member" to mean "[a] part configured to hold, grasp, or apply pressure to tissue that is movable and that works with a component of the instrument

[1] Ethicon does, however, make one argument that would require the court to construe the term "proximal end of the cutting surface." Oral Argument Tr. 29. The court addresses this argument in its likelihood of success analysis.

(e.g. the cutting jaw)." Id. at 125;

(3) "tissue engaging stops" to mean "the portions of the clamp that engage tissue and prevent tissue from moving past the proximal portion end of the blade surface." Tyco I, 411 F. Supp. 2d at 97; and

(4) "blade surface" to mean "the face that engages tissue to achieve cutting." Id. at 97. Judge Arterton construed "blade surface" in the context of a related patent, U.S. Patent No. 6,682,544 (the " '544 patent"), which, like the '286 patent, is entitled "Ultrasonic Curved Blade". Id. at 96. Courts "presume, unless otherwise compelled, that the same claim term in . . . related patents carries the same construed meaning." Omega Eng'g, Inc, v. Raytek Corp., 334 F.3d 1314, 1334 (Fed. Cir. 2003). Indeed, Judge Arterton acknowledged that the '544 and '286 patents were related and consistently construed another common term between them. See Tyco I, 411 F. Supp. 2d at 109.

After oral argument, Ethicon began to argue that the court should not issue a ruling without a "full claim construction inquiry." See Def.'s Supp. Mem. 2 n.3 (Doc. No. 82). The court disagrees. The claim construction from the Tyco litigation sufficiently resolves the meaning of claim 15 of the '286 patent. To the extent that Ethicon suggests additional claim construction, the court addresses it in its likelihood of success analysis.

3. Likely Infringement of Claim 15 of the '286 Patent

The parties fiercely dispute whether Ethicon's ACE+7 likely infringes claim 15 of the '286 patent. There is no dispute that the ACE+7 is an ultrasonic instrument with a handle and a vibration coupler connected to a cutting surface, so the limitations of parts

(a), (b), and (c) of claim 7 are met. The parties' disagreement centers on part (d) of claim 7's language that states, "the clamp member and the cutting jaw defining a tissue receiving area . . . and having a tissue engaging stop positioned to engage tissue and prevent positioning of tissue beyond the proximal end of the cutting surface of the cutting jaw," and on claim 15's requirement that the "cutting surface of the cutting jaw [be] curved." '286 Patent.

Covidien offers the opinion of Dr. William Durfee as the basis of its infringement theory. Dr. Durfee conducted tests with chamois, porcine kidney tissue, and paper in which he placed the testing material into the cutting jaw and observed that the materials contacted the clamp ears in such a way that the clamp ears prevented position of the material beyond the proximal end of the cutting surface. Durfee Decl. ¶¶ 50–60; Durfee Reply ¶¶ 7–10. Dr. Durfee acknowledges that Ethicon has included outer tube protrusions in the ACE+7 that, when the clamp member is open, extend distally past the clamp ears by about .23 millimeters. Durfee Decl. ¶ 47. However, he also states that as the clamp closes, the clamp ears eventually "extend distally beyond the outer tube such that the outer tube no longer protrudes past the clamp member." Id. ¶ 47. Further, using paper and an index card as an illustration, Dr. Durfee showed that even when the clamp is open, materials entering the cutting jaw from certain angles can pass the redesigned outer tube protrusions only to then be engaged by clamp ears. See Durfee Reply ¶¶ 7–10 & Figures 1–6. Significantly, he pointed out that the ACE+7 "is used in surgery on malleable and compressible tissue" so the "thin outer tube cannot realistically prevent tissue from engaging with the tissue stops on the clamp member." Durfee Decl. ¶ 50.

Regarding infringement of claim 15's requirement that the "cutting surface of the cutting jaw [be] curved," Dr. Durfee noted that Judge Arterton construed that phrase to mean "deviating from a straight line along the lengthwise dimension," and he showed a picture of how the ACE+7's cutting surface is curved in just that way. Id. ¶¶ 62–63 & Figure 21.

Ethicon disagrees with Dr. Durfee's infringement analysis and makes three non-infringement arguments. First, it claims that the ACE+7's outer tube protrusions define the proximal end of the cutting surface, and that the clamp ears are therefore not tissue stops. Second, it argues that the clamp ears do not prevent tissue from moving proximally along the blade surface. Finally, it argues that the clamp ears do not prevent tissue from moving beyond the proximal end of the curved cutting surface. The court addresses each argument in turn.

Ethicon first argues that the location of the ACE+7's outer tube protrusions defines the proximal end of the cutting surface, so the clamp ears cannot be tissue stops. See Def.'s Mem. Opp'n 17–20. To make this argument, Ethicon points to a sentence of the '286 patent's specification that states, "Clamp body includes a pair of tissue receiving stops that define the proximal end of the exposed blade surface." '286 Patent col.3 l.67–col.4 l.1. Ethicon then argues that the patentee was acting as its own lexicographer in the part of the sentence that states, "a pair of tissue receiving stops that define the proximal end of the exposed blade surface." See Def.'s Mem. Opp'n 17. According to Ethicon, the ACE+7's outer tube protrusions are the "pair of tissue receiving stops that define the proximal end of the exposed blade surface" because the protrusions are more distal than the clamp ears and there can only be one proximal

end. Id. at 19. Thus, Ethicon's argument goes, the ACE+7 avoids the limitation of claim 7(d) that the clamp member have a "tissue engaging stop" to prevent "positioning of tissue beyond the proximal end of the cutting surface" because the "proximal end of the exposed blade surface," defined by the outer tube protrusions, is distal to the clamp ears. Id. (In a footnote, Ethicon asserts the terms "proximal end of the exposed blade surface" and "proximal end of the cutting surface" mean the same thing, especially given Judge Arterton's construction of "blade surface" as "the face that engages tissue to achieve cutting." Id. at 18 n.5.)

Ethicon's argument fails. Generally, "[t]he words of a claim are . . . given their ordinary and customary meaning as understood by a person of ordinary skill in the art when read in the context of the specification." Thorner v. Sony Computer Entm't Am. LLC, 669 F.3d 1362, 1365 (Fed. Cir. 2012). As Ethicon points out, a patentee can change the meaning of a word in the claims by defining that word in the specification. See id. However, in order to do this, the patentee must both "clearly set forth a definition of the disputed term" and "clearly express an intent to redefine the term." Id. (internal quotation marks omitted). "It is not enough for a patentee to simply disclose a single embodiment or use a word in the same manner in all embodiments . . . ." Id.

Here, it is far from clear that the patentee intends the specification to define "proximal end of the exposed blade surface" as wherever the most distal tissue stops are located. First, the specification's use of the word "defines" does not appear to be a lexicographic one; instead, it appears the patentee is using the word in the sense of describing a physical boundary. Second, the sentence is describing a preferred embodiment. The sentence in the specification on which Ethicon primarily relies clearly

makes reference to tissue stops on the clamp body. '286 Patent col.3 l.67–col.4 l.1. At oral argument, counsel for Ethicon acknowledged that the sentence's reference to a "clamp body" was a description of the preferred embodiment, but he nonetheless maintained that the part of the sentence stating "a pair of tissue receiving stops that define the proximal end of the exposed blade surface" applies as a defined term throughout the patent. Oral Argument Tr. 78. If the patentee intended to define the "proximal end of the exposed blade surface" as Ethicon argues, it failed to clearly express such intent. See Thorner, 669 F.3d 1362 at 1365 ("[A] patentee must 'clearly express an intent' to redefine the term." (quoting Helmsderfer v. Bobrick Washroom Equip., Inc., 527 F.3d 1379, 1381 (Fed. Cir. 2008)).

Moreover, even accepting that the patentee intended to act as its own lexicographer with this sentence, it is not clear why the most distal tissue stops – the outer tube protrusions – would define the "proximal end of the exposed blade surface," instead of the most proximal tissue stops – the clamp ears. This is especially unclear where, as here, the more distal "tissue stops" do not stop all the tissue. Reading the sentence as a whole, the latter interpretation makes far more sense: the sentence is describing a "clamp body," and it mentions the "exposed blade surface." '286 Patent (emphasis added). The outer tube protrusions are not on the clamp body, and the ACE+7's blade surface is exposed proximal to the outer tube protrusions, so it is difficult to understand how the protrusions are defining the "proximal end of the exposed blade surface." Notably, Ethicon's counsel acknowledged that "some cutting might occur proximal to" the most distal tissue stops, i.e., the outer blade protrusions. Oral Argument Tr. 78. In light of Judge Arterton's construction of "blade surface" as "the face

that engages tissue to achieve cutting," Ethicon's theory that the most distal tissue stop defines the blade surface makes little sense. Ethicon points to other statements in the specification in support of its theory, see Cimino Decl. 26–28, but these statements reveal the same flaws: Covidien was not clearly acting as its own lexicographer and, even if it was, Ethicon's interpretation of that lexicography is unconvincing.

Ethicon next argues that the "ears of the clamp arm do not prevent tissue from moving along the 'blade surface.'" Def.'s Mem. Opp'n 20. Ethicon points out that "the outer tube protrusions . . . not only extend distally beyond the ears of the clamp arm . . . , they also ride inside the clamp arm relative to the blade surface, while the ears of the clamp arm are located outside the outer tube. As a result, the outer tube protrusions are the structure most adjacent to the blade surface." Id. 20–21 (internal citation omitted). Therefore, according to Ethicon, even if the clamp ears engage tissue, "they can only prevent it from moving proximally along the *sides* of the blade or the sides of the outer tube." Id. at 21 (emphasis in original).

It is not entirely clear why claim 7 requires that the tissue stops on the clamp ears prevent tissue from moving along the blade surface. The relevant language of claim 7 of the '286 patent simply states that the device has "a tissue engaging stop positioned to . . . prevent positioning of tissue beyond the proximal end of the cutting surface." Judge Arterton's claim construction of "tissue engaging stops" does not use the word "along." See Tyco I, 411 F. Supp. 2d at 97. Ethicon argues that the words "beyond" and "along" in the context of a blade surface mean the same thing. See Oral Argument Tr. 72 ln. 13–16. The court does not see why this is necessarily the case. The claim's language refers to the tissue stops preventing tissue from moving beyond a set point,

i.e., the proximal end of the cutting surface. The reasons for having tissue stops that prevent tissue from moving beyond the end of the cutting surface may well be different from those for having stops that prevent tissue from moving along the blade surface.

In any event, it seems likely that the clamp ears of the ACE+7 do prevent tissue from moving along the blade surface. It is true both that the outer tube protrusions extend distally beyond the clamp ears and that they are closer or more adjacent to the blade surface than the clamp ears. See Schulte Decl. ¶¶ 23–24. However, there are still gaps between the outer tube protrusions and the blade surface. Dr. Durfee was able to slide an index cast past the outer tube protrusions such that it was touching at least one of the clamp ears and the blade surface. See Durfee Reply ¶¶ 10, 19, Figures 1–6. While an index card is thinner than the tissue that the device will typically engage, and Dr. Durfee may have been sliding the index card into the cutting jaw at specific angles, tissue is malleable, and the court fails to see why tissue would not squeeze through the gaps between the outer tube protrusions, slide along the blade, and ultimately press against the clamp ears. Ethicon's counsel acknowledged that "some cutting might occur proximal to" the outer tube protrusions. Oral Argument Tr. 78. The only part of the device that could prevent tissue from moving along the blade surface proximal to the outer tube protrusions is the clamp ears.

Finally, Ethicon argues that claim 15 of the '286 patent requires "a tissue engaging stop on the clamp arm" to "prevent the movement of tissue beyond the proximal end of the *curved* portion of the cutting jaw." Def.'s Mem. Opp'n 22 (emphasis in original). To make this argument, Ethicon takes the language of claim 15, which states that "the cutting surface of the cutting jaw is curved," and reads it into claim 7,

which requires that the clamp member have a tissue stop to "prevent positioning of tissue beyond the proximal end of the cutting surface of the cutting jaw." See id. at 22–23.

Claim preclusion bars Ethicon from making this argument. "The doctrine of res judicata, or claim preclusion, holds that a final judgment on the merits of an action precludes the parties or their privies from relitigating issues that were or could have been raised in that action." Monahan v. N.Y. City Dep't of Corr., 214 F.3d 275, 284 (2d Cir. 2000). Claim preclusion applies if "(1) the previous action involved an adjudication on the merits; (2) the previous action involved the [same parties] or those in privity with them; [and] (3) the claims asserted in the subsequent action were, or could have been raised in the prior action." Id. at 285. In patent cases, claim preclusion can only apply where the "accused device in the action before the court is 'essentially the same' as the accused device in a prior action between the parties that was resolved by a judgment on the merits." Acumed LLC v. Stryker Corp., 525 F.3d 1319, 1324 (Fed. Cir. 2008). "Accused devices are 'essentially the same' where the differences between them are merely 'colorable' or 'unrelated to the limitations in the claim of the patent.'" Id. (quoting Foster v. Hallco Mfg. Co., Inc., 947 F.2d 469, 480 (Fed. Cir. 1991)). "If . . . the accused device of the second suit remains unchanged with respect to the corresponding claim limitations at issue in the first suit," then claim preclusion applies. Nystrom v. Trex Co., Inc., 580 F.3d 1281, 1285–86 (Fed. Cir. 2009) (emphasis added).

Ethicon has changed the ACE+7 from those devices previously deemed infringing by adding the outer tube protrusions and by changing the clamp ears. However, Ethicon has not changed the design of the blade itself. See Durfee Reply ¶¶

24–28 & Figures 9–11; Oral Argument Tr. 38 ln. 6–7 ("It is the same blade . . . ."). It now argues that the blade design does not infringe the '286 patent because claim 15 requires the "cutting surface of the cutting jaw to be curved," and there is a portion of the cutting surface which is straight. However, this was true of Ethicon's devices deemed to infringe in the prior litigation. See Durfee Reply ¶ 27. It could have made this argument in that litigation, but it did not. Indeed, Ethicon's counsel candidly admitted that they missed the argument because of the amount of claims in the litigation. Oral Argument Tr. 83 ("With 42 claims at issue in the case, your Honor, you don't think of everything."). Thus, claim preclusion bars Ethicon from raising this theory of non-infringement.

Claim preclusion aside, the court is not convinced by Ethicon's non-infringement argument. Claim 7, on which claim 15 depends, requires that the clamp member have a tissue stop that "prevent[s] positioning of tissue beyond the proximal end of the cutting surface." '286 Patent. For the reasons already discussed, on the record before the court the ACE+7's clamp ears perform such a function. Claim 15 requires that "the cutting surface of the cutting jaw" be "curved along the longitudinal axis of the instrument." Id. Ethicon concedes, and the court agrees, that the ACE+7's blade is curved. Oral Argument Tr. 79. Thus, the ACE+7 meets independent claim 7's requirements and dependent claim 15's requirements. It is true that some small portion of the blade is straight distal to the most proximal tissue stop; however, the blade as a whole is clearly curved.

Therefore, on the record before the court, Covidien has shown, and Ethicon has failed to refute, a strong likelihood of success on the merits of its infringement claim.

B. Irreparable Harm

1. Issue Preclusion Does Not Apply

At the threshold, Ethicon asserts that issue preclusion bars Covidien from arguing that Ethicon's infringement of claim 15 caused it irreparable harm. As stated above, issue preclusion applies if: "(1) the issue is identical to one decided in the first action; (2) the issue was actually litigated in the first action; (3) resolution of the issue was essential to a final judgment in the first action; and (4) the party against whom estoppel is invoked had a full and fair opportunity to litigate the issue in the first action." Innovad Inc. v. Microsoft Corp., 260 F.3d 1326, 1334 (Fed. Cir. 2001).

In the Tyco litigation, Judge Arterton denied Covidien's request to permanently enjoin Ethicon from selling certain devices that infringed claim 15 of the '286 patent. Tyco IV, 936 F. Supp. 2d at 86. However, the ACE+7 was not at issue in that litigation. The issue before the court is not whether Ethicon's infringement of claim 15 in the abstract causes irreparable harm to Covidien, and that was not issue in the Tyco litigation. Rather, the issue is whether Ethicon's infringement of claim 15 with respect to a certain device – here, the ACE+7 – causes irreparable harm to Covidien. Because the devices at issue before the court in the Tyco litigation were different from the ACE+7, the issues were not identical, so issue preclusion does not apply.

The differences between the ACE+7 and the previous devices are significant too: the ACE+7 allows surgeons to seal vessels up to seven millimeters in size, while Ethicon's previous curved-blade devices could only seal up to five millimeters. See Chindlund Decl. ¶ 48. This change increases the potential harm to Covidien because Ethicon can now market its infringing product to more consumers and compete directly

with Covidien's devices that seal vessels up to seven millimeters.

2. The ACE+7 and Irreparable Harm

a. Irreparable Harm to Covidien

A plaintiff seeking a preliminary injunction must "demonstrate that irreparable injury is likely in the absence of an injunction." Winter v. Natural Res. Def. Council, Inc., 555 U.S. 7, 22 (2008). To show irreparable harm on a preliminary injunction in a patent infringement case, "a patentee must establish . . . : 1) that absent an injunction, it will suffer irreparable harm, and 2) that a sufficiently strong causal nexus relates the alleged harm to the alleged infringement." Apple Inc. v. Samsung Electronics Co., 695 F.3d 1370, 1374 (Fed. Cir. 2012). "Price erosion, loss of goodwill, damages to reputation, and loss of business opportunities are all valid grounds for finding irreparable harm." Celsis In Vitro, Inc. v. CellzDirect, Inc., 664 F.3d 922, 930 (Fed. Cir. 2012). In Celsis In Vitro, the Federal Circuit recognized that the inability to accurately measure all lost sales or growth as a result of an infringing competitor is a factor to consider in the irreparable harm analysis. See id. (upholding the district court's finding of irreparable harm and noting that the "mere possibility of monetary damages does not defeat a motion for preliminary injunction"). Other factors to consider in the irreparable harm analysis include the size and structure of the market, the likelihood of losing customers and market share, and the degree to which the infringer competes with the plaintiff. See Trebro Mfg., Inc. v. Firefly Equip., LLC, 748 F.3d 1159, 1170–71 (Fed. Cir. 2014). Covidien argues that it has lost, and will continue to lose, market share, goodwill, reputation, and business opportunities as a result of Ethicon's infringement of claim 15 with sales of its ACE+7.

In order to explain the irreparable harm analysis, it is necessary to briefly discuss the relevant market and the parties' product offerings. "Covidien and Ethicon are the two largest manufacturers of laparoscopic advanced energy surgical devices." Chindlund Decl. ¶ 7. Covidien accounts for approximately REDACTED% of that market, and Ethicon accounts for approximately REDACTED%. Id. "All other companies account[ ] for approximately REDACTED%" of the market, "with Olympus America accounting for a significant portion." Id. Devices within this market use a variety of energy sources for cutting or sealing. See id. ¶ 6. Most relevant here are ultrasonic and advanced bipolar radiofrequency ("RF") energies. These energy sources generally compete, see Lee Decl. ¶ 29, but some physicians may prefer one over the other, see Pickron Decl. ¶ 13. The parties dispute the degree to which these energy sources are interchangeable. Compare Lessek Decl. ¶ 13 ("While some types of surgeons use ultrasonic and RF bipolar modalities interchangeably, ultrasonic and RF instruments are not strictly competitive or interchangeable.") with Lee Decl. ¶ 29 ("The ACE+7 has the same procedural applications as the LigaSure . . . .").

Covidien markets the LigaSure line of products, the majority of which uses RF energy. Chindlund Decl. ¶¶ 9–10. All of the LigaSure products are cleared for sealing vessels up to seven millimeters in size. Id. ¶ 11. Among others, Ethicon markets the Harmonic ACE line of products, which uses ultrasonic energy. Id. ¶ 27. Until the ACE+7's release, all of Ethicon's Harmonic ACE products were only indicated for sealing vessels up to five millimeters. Id. ¶ 30. The ACE+7, however, is indicated for sealing vessels up to seven millimeters. Id.

Covidien asserts that "sales of the ACE+7 will negatively impact Covidien's

market share more than ever possible, because the ACE+7 is indicated for sealing vessels up to 7 mm in size and Ethicon has specifically targeted LigaSure in relation to large vessel sealing." Id. ¶ 57. Covidien has pointed to a variety of Ethicon's marketing material that directly compares the ACE+7 to LigaSure products, including Ethicon's public-facing ACE+7 website. See Ethicon, HARMONIC ACE®+7 Shears with Advanced Hemostasis, http://www.ethicon.com/healthcare-professionals/products/advanced-energy/harmonic/harmonic-ace-plus-seven (last visited Oct. 10, 2014). Moreover, Covidien argues that "Ethicon will use the ACE+7 to leverage its position in the advanced energy market and to increase sales across products in Ethicon's advanced energy portfolio." Id. ¶ 57; see also Lee Decl. ¶ 30 ("It is my understanding that based on these contractual relationships, the selection of one energy-based device may drive the purchase of other types of energy-based devices from the same company."). Covidien's expert, John Chindlund, predicts that "Covidien could lose as much as 5 to 10 percentage points of market share of the vessel sealing and dissection market in the next 12 month if Ethicon is effective in targeting the infringing ACE+7 against Covidien's LigaSure product line." Chindlund Reply ¶ 8. He also explained how lost market share and sales could have lasting and potentially irreversible impacts on Covidien's negotiating power based on the way the industry's long-term contract negotiations work. See id. ¶¶ 9–13. Notably, Mr. Chindlund was able to point to specific examples of hospitals in the process of replacing LigaSure devices with ACE+7 devices within months of the ACE+7's introduction. Id. ¶ 15. Finally, Covidien points out that Ethicon's marketing of the ACE+7 and its infringing curved blade falsely gives consumers the impression that Ethicon was the innovator of

that feature, see Chindlund Decl. ¶¶ 59–60, thus damaging or diminishing Coidien's reputation. Covidien has made a clear showing that it is likely to suffer irreparable harm.

b. Causal Nexus between Infringement and Irreparable Harm

Regarding the causal nexus requirement, the Federal Circuit has explained that the patentee:

> must show some connection between the patented feature and demand for [the infringing] products. There might be a variety of ways to make this required showing, for example, with evidence that a patented feature is one of several features that cause consumers to make their purchasing decisions. It might also be shown with evidence that the inclusion of a patented feature makes a product significantly more desirable. Conversely, it might be shown with evidence that the absence of a patented feature would make a product significantly less desirable.

Apple Inc. v. Samsung Electronics Co., 735 F.3d 1352, 1364 (Fed. Cir. 2013).

Covidien has also shown a causal nexus between Ethicon's infringement of claim 15 of the '286 patent and its likely irreparable harm. Ethicon acknowledges "that a curved blade is a feature some surgeons may prefer." Def.'s Mem. Opp'n 29. Indeed, in the Tyco litigation, Judge Arterton found that "consumers valued the curved blades." Tyco VI, 936 F. Supp. at 72. Also convincing is the fact that Ethicon has promoted the ACE+7's curved blade. Chindlund Decl. ¶ 32, Ex. A. While Ethicon seldom uses the word "curved" in its marketing material, it often lauds the ACE+7's blade's precision, which, according to Ethicon, is a result of the curved blade's design. Id. (showing Ethicon's website stating "[j]aw and curved blade are uniquely designed for precise dissection, sealing and transection"). Indeed, the very fact that Ethicon chose to use the curved blade in the ACE+7 suggests how valuable the feature is to consumers. Ethicon must have known the risk of including the curved blade given the result of the

Tyco litigation, and it could have simply used a straight blade, as it already does in one of its other Harmonic products. See Tyco VI, 936 F. Supp. at 75 n.24. Ethicon would have had little reason to take on the risk of infringing if the curved blade was not a desirable feature to consumers.

Covidien has established that there is a causal nexus between Ethicon's infringement of claim 15 of the '286 patent and the irreparable harm it is likely to suffer.

C. Balance of the Equities

Covidien argues that the equities weigh in its favor because Ethicon knowingly undertook the risk of infringement in marketing its ACE+7. Ethicon argues that the equities weigh in its favor because it has invested considerable time and money developing and marketing the ACE+7, and because Covidien does not practice its patent.

"The district court must balance the harm that will occur to the moving party from the denial of the preliminary injunction with the harm that the non-moving party will incur if the injunction is granted." Hybritech Inc. v. Abbott Labs., 849 F.2d 1446, 1457 (Fed. Cir. 1988). The court may issue a preliminary injunction where, after carefully considering the question, "neither party has a clear advantage." Id. at 1457–58. One relevant factor to the equitable balancing is whether the infringer took a calculated risk in selling a product that may infringe a known patent. See Celsis In Vitro v. CellzDirect, Inc., 664 F.3d 922, 931 (Fed. Cir. 2012).

Absent a preliminary injunction, Covidien will suffer those harms identified in the irreparable harm analysis, including loss of market share and goodwill. Balanced against these hardships are those that Ethicon will suffer if it is enjoined from selling the

ACE+7. Ethicon has certainly spent a substantial amount of resources designing and marketing the ACE+7. See Lessek Decl. ¶ 26. If enjoined, Ethicon will be largely unable to reap the rewards of those expenditures. See id. ¶ 27. Thus, both sides present hardships in the face of a contrary ruling.

Here, the balance of hardships weighs in Covidien's favor. Although Ethicon has doubtless spent significant amounts of time and money bringing the ACE+7 to market, it did so knowing of claim 15 of the '286 patent. Indeed, Ethicon's attempt to design around the '286 patent shows that it was aware of and understood the risk of infringement. See Schulte Decl. ¶ 7. Notably, Ethicon already sold ultrasonic devices with straight blades. See Tyco VI, 936 F. Supp. 2d at 75 n.24. It could have simply used a straight blade in the ACE+7, but it chose to take the risk of using the curved blade and relying on the non-infringement arguments addressed above.

The fact that Covidien does not practice the patent does not to shift the equities in favor of Ethicon. Even if a patentee's choice not to practice its patent is a relevant consideration to the balance of the equities,[2] it does not outweigh the equities in favor of Covidien in this case. While Covidien does not use a curved blade on any of its ultrasonic devices – which is the type of device taught by claim 15 of the '286 patent – it does use a curved blade on some of its RF products. See Oral Argument Tr. 5–6 ("[Covidien] has a LigaSure with a curved blade.") Thus, even though none of

[2] Ethicon cites Edwards Lifesciences AG v. CoreValve, Inc., 699 F.3d 1305, 1315 (Fed. Cir. 2012), in support of its argument that Covidien's failure to practice its patent shifts the equities in its favor. However, the Federal Circuit in Edwards merely quoted a district court's observation that "[c]ourts awarding permanent injunctions typically do so under circumstances where the plaintiff practices its invention and is a direct market competitor." Id. (quoting Advanced Cardiovascular Sys., Inc. v. Medtronic Vascular, Inc., 579 F. Supp. 2d 554, 558 (D. Del. 2008), dismissed, 356 F. App'x 389 (Fed. Cir. 2009)). The Federal Circuit did not appear to endorse or criticize this observation: it simply stated it to explain the patentee's argument in the case.

Covidien's devices meet all of claim 15's limitations, Covidien does practice the curved blade, and it is infringement of that feature that Covidien bases its theory of irreparable harm. Even if Covidien did not use a curved blade, however, this factor alone would not be enough to outweigh the equities favoring Covidien on the record before the court.

Covidien and Ethicon are indisputably fierce competitors. Covidien should not be burdened by competition against its own intellectual property.

D. The Public Interest

Covidien emphasizes the importance of enforcing patents according to the scheme contemplated by the Constitution. Ethicon argues that the public interest favors availability of medical devices. Both rely on important, albeit broad, public interest considerations.

"Although the public interest inquiry is not necessarily or always bound to the likelihood of success of the merits, . . . absent any other relevant concerns, . . . the public is best served by enforcing patents that are likely valid and infringed." Abbott Labs. v. Andrx Pharm., Inc., 452 F.3d 1331, 1348 (Fed. Cir. 2006). Indeed, even where other important concerns are present, the public interest may be best served by granting an injunction. See Abbott Labs. v. Sandoz, Inc., 544 F.3d 1341, 1362–63 (Fed. Cir. 2008). Thus, the Federal Circuit has recognized "the significant public interest in encouraging investment in drug development and protecting the exclusionary rights conveyed in pharmaceutical patents." Id. (internal quotations marks omitted).

On the other hand, the Federal Circuit has recognized that there is a strong public interest in the availability of medical products. See, e.g., Datascope Corp. v. Kontron Inc., 786 F.2d 398, 401 (Fed. Cir. 1986) (upholding preliminary injunction denial

based, in part, on the finding that "the public will be harmed by an injunction in that some physicians prefer" the defendant's medical product); Cordis Corp. v. Boston Scientific Corp., 99 F. App'x 928, 935 (Fed. Cir. 2004) ("[A] strong public interest supports a broad choice of drug-eluting stents, even though no published study proves the superiority of either Cordis's Cypher or BSC's Taxus stent.").

Of course, no blanket rule makes medical products immune from preliminary injunctions. See Hybritech Inc. v. Abbott Labs., 849 F.2d 1446, 1458 (Fed. Cir. 1988) (affirming the district court's decision to enjoin the sale of some medical products but not others). Rather, courts have considered a number of factors in deciding whether enjoining the sale of a particular medical device would harm the public interest, including how new the infringing product is, see Smith & Nephew, Inc. v. Biomet, Inc., 05-611-KI, 2005 WL 3132313, at *19 (D. Or. Nov. 21, 2005), whether the product involved cutting edge medical treatments, 3M Unitek Corp. v. Ormco Co., 96 F. Supp. 2d 1042, 1052 (C.D. Cal. 2000), and the degree to which alternatives to the product exist, Hybritech Inc v. Abbott Labs., CV 86-7461, 1987 WL 123997 (C.D. Cal. July 14, 1987), aff'd, 849 F.2d 1446 (Fed. Cir. 1988).

Importantly, courts denying a preliminary injunction on the ground that the infringing product is related to medical treatment often rely on some exacerbating circumstance not present here. For example, the district court in Hybritech denied preliminary injunction only as to those that products that dealt with cancer treatment, substitution of which would have set cancer patients back, and those for which the patentee provided no alternative. Id. at n.17 and accompanying text. In another instance, the district court in Cordis appeared to rely on severe concerns about supply

of the allegedly infringing product and the fact that only one prong of the preliminary injunction analysis favored the plaintiff-patentee. See Cordis Corp., 99 F. App'x at 932 ("The trial court noted that the injunction would . . . affect the worldwide supply of [the product at issue]. . . . [T]he district court reasoned that grant of the injunction would harm the public interest because [the plaintiff-patentee] cannot ensure an adequate supply.").

The court concludes that enforcing Covidien's patent is in the public interest. It is especially important to enjoin infringement where, as here, it was consciously undertaken by one who knew of the risk. While Ethicon has put forward an important public interest factor of its own, it does not outweigh those offered by Covidien. Any harm to the public as a result of an injunction against Ethicon's sale of the ACE+7 is limited by the fact that the ACE+7 is a new device and by the availability of alternative devices. The ACE+7 has only been on the market "for a few months." Def.'s Mem. Opp'n 35; see also Pickron Decl. ¶ 16 ("Ethicon just recently began offering the ACE+7."). While the record shows that some physicians may prefer the ACE+7 for one reason or another, see, e.g., Pickron Decl. ¶ 18, it also shows that alternatives to the ACE+7 exist, see, e.g., Lee Decl. ¶ 29 ("The ACE+7 has the same procedural applications as the LigaSure and Thunderbeat . . . ."). Although physicians' preferences are relevant to the public interest analysis, see Datascope Corp., 786 F.2d at 401, they are not necessarily dispositive, particularly where, as here, the device is so new that any preference for it is unlikely to be deeply held or widespread. Moreover, to the extent Ethicon denies that RF energy (used by Covidien's competing LigaSure) is a substitute for ultrasonic energy (used by ACE+7), its argument is belied by the degree

to which it compares its ACE+7 to Covidien's LigaSure products in its marketing. See Lee Decl. ¶ 27 ("In response to my use of the LigaSure device, the [Ethicon] salesperson positioned the ACE+7 as an ultrasonic substitute with similar sealing capability on large vessels.").

Given that the ACE+7 has only recently been released and the fact that physicians have alternatives available, the public interest is better served here by enjoining Ethicon's infringement.

E. Stay Pending Appeal

Finally, Ethicon argues that, instead of issuing a preliminary injunction, the court should stay the proceeding pending the Federal Circuit's disposition of the parties' appeals from the Tyco litigation. "[T]he decision whether to issue a stay is firmly within a district court's discretion." LaSala v. Needham & Co., Inc., 399 F. Supp. 2d 421, 427 (S.D.N.Y. 2005) (internal quotations marks omitted). Courts in the Second Circuit have considered five factors in determining whether a stay is warranted: "(1) the private interests of the plaintiffs in proceeding expeditiously with the civil litigation as balanced against the prejudice to the plaintiffs if delayed; (2) the private interests of and burden on the defendants; (3) the interests of the courts; (4) the interests of persons not parties to the civil litigation; and (5) the public interest." Catskill Mountains Chapter of Trout Unlimited, Inc. v. United States EPA, 630 F. Supp. 2d 295, 304 (S.D.N.Y. 2009); see also Cherokee Nation of Oklahoma v. United States, 124 F.3d 1413, 1416 (Fed. Cir. 1997) ("In deciding to stay proceedings indefinitely, a trial court must first identify a pressing need for the stay. The court must then balance interests favoring a stay against interests frustrated by the action. Overarching this balancing is the court's paramount obligation to exercise jurisdiction timely in cases properly before it.").

For essentially the same reasons that the court grants Covidien's Motion for Preliminary Injunction, the court denies Ethicon's request to stay the proceedings. Covidien applied for a preliminary injunction specifically because it has an interest in expeditiously enforcing the '28 patent. Covidien will suffer more than mere prejudice if the proceedings are delayed: it will likely suffer irreparable harm. For reasons already discussed, the public interest (and, consequently, the interests of persons not parties to the litigation) favors a preliminary injunction, not a stay. The court acknowledges that Ethicon is burdened by the preliminary injunction; presumably, so is any party that is enjoined from doing what it otherwise would. Covidien's success on its Motion for Preliminary Injunction shows why this burden is justified. If Ethicon ultimately succeeds on its appeal on validity, which is its basis for arguing that this court should stay the proceedings, then the injunction will be vacated and the burden to Ethicon limited.

V. CONCLUSION

For the foregoing reasons, the court **GRANTS** Covidien's Motion for Preliminary Injunction (Doc. No. 45). An Order stating the terms of the injunction will follow.

A telephonic conference is scheduled for 5:00 p.m. on Thursday, October 16, 2014, to discuss the bond. Before that conference, the parties should confer to discuss and agree upon an appropriate bond amount. If the parties cannot agree, they should submit their proposed amounts in separate filings. The Preliminary Injunction will not take effect until bond has been posted.

SO ORDERED.

Dated at New Haven, Connecticut, this 15th day of October, 2014.

/s/ Janet C. Hall
Janet C. Hall
United States District Judge

UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

COVIDIEN SALES LLC and COVIDIEN LP, f/k/a TYCO HEALTHCARE GROUP LP and UNITED STATES SURGICAL CORP., Plaintiffs,	:	CIVIL ACTION NO. 3:14-cv-917 (JCH)
v.	:	REDACTED
ETHICON ENDO-SURGERY, INC., Defendant.	:	OCTOBER 22, 2014

RULING [REDACTED] RE: PRELIMINARY INJUNCTION CONDITIONS

I. INTRODUCTION

Having granted the Motion for Preliminary Injunction (Doc. No. 45) filed by Covidien Sales LLC and Covidien LP (collectively "Covidien"), see Ruling Re: Motion for Preliminary Injunction (Doc. No. 97), the court must now determine an appropriate bond amount and whether a stay or "sunset" period is warranted. For the reasons that follow, Covidien is ordered to post a bond of five million dollars ($5,000,000) through December 31, 2014, and the injunction will go into effect immediately after the bond is posted.

II. DISCUSSION

A. Bond Amount

Rule 65(c) of the Federal Rules of Civil Procedure states: "The court may issue a preliminary injunction . . . only if the movant gives security in an amount that the court considers proper to pay the costs and damages sustained by any party found to have been wrongfully enjoined or restrained." District courts have wide discretion to set a bond amount. See Doctor's Associates, Inc. v. Distajo, 107 F.3d 126, 136 (2d Cir.

1997). The law of the district court's regional circuit determines the amount of the bond. Int'l Game Tech. v. WMS Gaming, Inc., 1999 WL 717801, at *1 n.1 (Fed. Cir. 1999); see also Sanofi-Synthelabo v. Apotex Inc., 488 F. Supp. 2d 317, 349 (S.D.N.Y. 2006) ("[T]his Court has found no authority from the Federal Circuit governing the parameters for the amount of bond . . . ."), aff'd, 470 F.3d 1368 (Fed. Cir. 2006). When setting the bond amount, relevant considerations include "potential lost profits, lost market share and associated costs of relaunch." Sanofi-Synthelabo, 470 F.3d at 1385. "The party against whom a preliminary injunction is sought has the burden of establishing the amount of a bond necessary to secure against the wrongful issuance of the injunction." Elite Licensing, Inc. v. Thomas Plastics, Inc., 250 F. Supp. 2d 372, 391 (S.D.N.Y. 2003) (citing Doctor's Associates, Inc. v. Stuart, 85 F.3d 975, 985 (2d Cir. 1996)).

Covidien proposes a bond amount of three million dollars through December 31, 2014. Ethicon Endo-Surgery, Inc. ("Ethicon") proposes that the court require Covidien to cover all costs suffered by Ethicon. Alternatively, Ethicon proposes a bond amount of $300 million.

Ethicon states that, by the end of 2014, the injunction will result in its loss of at least XXX million dollars in incremental profits from U.S. sales, at least XXX million dollars in incremental profits on international sales of the ACE+7 that were to be manufactured, in part, in the U.S., and $XXX in costs associated with relaunching the product. See Lessek Preliminary Injunction Terms Decl. ¶¶ 12, 19, 25. It also alleges harm to its reputation, goodwill, and customer relationships.[1] Id. 20–23. Using these

[1] Ethicon does not suggest a dollar figure of this harm, and it provides no evidence from which

numbers, the court concludes that a bond of five million dollars through December 31, 2014, is reasonable based on the record before the court. If the Federal Circuit has not ruled claim 15 of the '286 patent invalid in the Tyco litigation by that time, the court will revisit the bond amount at the end of the year.[2]

B. Timing of the Injunction

Ethicon argues that the court should stay the preliminary injunction until the Federal Circuit rules on its appeal or, alternatively, until the Federal Circuit can rule on a stay. It also argues that the court should allow for a 45-day sunset period in order to minimize disruption in its business while it implements the injunction. Covidien urges the court to issue the injunction immediately upon its posting of the bond.

The court declines to delay the injunction any further.[3] Ethicon's arguments in support of its request for a sunset period are unconvincing. First, Ethicon seems to express concern at the difficulty of existing ACE+7 users having to replace their devices. See Lessek Preliminary Injunction Terms Decl. ¶¶ 5–6. The court's injunction does not enjoin customers who already own the ACE+7 from using it. Second, Ethicon states that it takes "approximately XXX weeks to manufacture, package and sterilize an ACE+ device," which it suggests physicians will consider as an alternative to the

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the court could reasonably estimate such a figure.

[2] As to Ethicon's request for an indefinite undertaking, the court is skeptical that Rule 65(c) contemplates an indefinite bond amount. This would undercut one of the central rationales for Rule 65's bond requirement: to provide the plaintiff with notice of its maximum liability. Nokia Corp. v. InterDigital, Inc., 645 F.3d 553, 557 (2d Cir. 2011) ("[T]he bond provides the plaintiff with notice of the maximum extent of its potential liability.").

Ethicon cites two cases in which a district court has required a party to post an undertaking instead of a bond with a set amount. These cases are not from this district, and they contain no analysis of the issue. See Johnson & Johnson v. Am. Home Products Corp., CIV. A. 94-1388, 1996 WL 39445, at *1 (E.D. Pa. Feb. 1, 1996); S.C. Johnson & Son, Inc. v. Clorox Co., 930 F. Supp. 753, 786 (E.D.N.Y. 1996). This court is unpersuaded by Ethicon's argument in this regard.

[3] The court granted the preliminary injunction on October 15, 2014.

ACE+7. Id. ¶ 8. However, Ethicon also acknowledges that it "has an existing inventory of the ACE+ in stock" and that it "expects to be able to avoid going into back order." Id. ¶ 9. Third, as Ethicon candidly recognizes, the ACE+ is a "candidate for doctors to use as an alternative" to the ACE+7. Id. ¶ 7. While the ACE+7 may have advantages over other devices, hospitals are not without alternatives. Indeed, the ACE+7 is a relatively new product, and hospitals that were considering ordering the device can instead use the products they were using just months earlier. See Ruling Re: Motion for Preliminary Injunction 26. Further, Ethicon cites no cases in which a district court delayed the enforcement of a preliminary injunction. While circumstances might exist to justify such delay, this court does not find those here. Finally, to the extent that Ethicon presents any valid concerns, it has had several days since the court issued its Ruling Re: Motion for Preliminary Injunction to begin addressing them.

Ethicon also seeks a more indefinite stay of the preliminary injunction (after which it would presumably seek an additional delay), pending either the Federal Circuit's decision on a stay application or its decision of Ethicon's appeal of the preliminary injunction. The court declines to grant a stay. The court is mindful of the factors in involved in a decision to grant a stay pending appeal. See Hilton v. Braunskill, 481 U.S. 770, 776 (1987). The court has already outlined the merits of Covidien's case and the harms that Covidien suffers as a result of the ACE+7's curved blade. See Ruling Re: Motion for Preliminary Injunction 16–21. Further, the equities of the case weigh against granting an indefinite stay for the benefit of a party who released a product that posed a substantial risk of infringement while one of its central non-infringement arguments remained undecided on appeal.

The validity issue is, without doubt, an important one that bears heavily on the rights' of the parties. However, unlike the Federal Circuit, this court is unwilling and unable to conduct what would essentially be an appellate review of a final judgment of a district court. This was reflected in the court's analysis of the validity of claim 15 of the '286 patent, and in the court's decision to deny a stay pending Ethicon's appeal from the Tyco litigation. See Ruling Re: Motion for Preliminary Injunction 5–6, 27–28. A district court is ill-equipped to assess the merits of a party's arguments on appeal from the final judgment of another district court. If there are substantial questions as to the validity of claim 15 of the '286 patent, the Federal Circuit will limit the harm to Ethicon by staying or, ultimately, vacating the injunction.

III. CONCLUSION

For the foregoing reasons, the court GRANTS in part and DENIES in part Covidien's Proposed Bond Amount for the Preliminary Injunction (Doc. No. 98). The court DENIES Ethicon's Motion on the Appropriate Terms of the Preliminary Injunction (Doc. No. 102), and it DENIES Ethicon's Motion to Stay the Preliminary Injunction Pending Appeal (Doc. No. 103).

The court will enter a separate Order setting forth the terms of the preliminary injunction.

SO ORDERED.

Dated at New Haven, Connecticut, this 22nd day of October, 2014.

/s/ Janet C. Hall
Janet C. Hall
United States District Judge

UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

COVIDIEN SALES LLC and COVIDIEN LP, f/k/a TYCO HEALTHCARE GROUP LP and UNITED STATES SURGICAL CORP., Plaintiffs,	:	CIVIL ACTION NO. 3:14-cv-917 (JCH)
v.	:	
ETHICON ENDO-SURGERY, INC., Defendant.	:	OCTOBER 22, 2014

ORDER GRANTING PLAINTIFFS'
MOTION FOR PRELIMINARY INJUNCTION (Doc. No. 45)

This matter having come before the court on the Motion for Preliminary Injunction (Doc. No. 45) filed by Plaintiffs COVIDIEN SALES LLP, COVIDIEN LP f/k/a TYCO HEALTHCARE GROUP LP and UNITED STATES SURGICAL CORPORATION (together "Covidien"); and the court, having carefully considered all of the papers filed in support of and in opposition to, and related to, Covidien's Motion for Preliminary Injunction, and having heard oral argument on the matter, concludes that Covidien has demonstrated that it is entitled to preliminary injunctive relief.

Accordingly, IT IS HEREBY ORDERED THAT:

(1) Covidien's Motion for Preliminary Injunction (Doc. No. 45) is GRANTED;

(2) Until such time as the court makes a final ruling on the merits, or until is otherwise ordered by the court, Ethicon, its respective agents, officers, employees, successors, and all persons acting in concert with each or any of them are hereby ENJOINED and RESTRAINED from making, using, offering

to sell or selling the accused ACE+7 product with a curved blade, as claimed in Claim 15 of US. Patent No. 6,468,286 (the " '286 patent");

(3) Notwithstanding the foregoing, Ethicon is not enjoined or restrained from:

(a) Making, using, offering to sell or selling a modified version of the ACE+7 product without a curved blade, such as the "straight blade" designs of Ethicon's ultrasonic surgical products that are immune from patent infringement liability (e.g., the LCSK5 and LCSB5), pursuant to a prior settlement agreement between the parties; or

(b) Making, using, offering to sell or selling a version of the ACE+7 product that otherwise avoids infringement of Claim 15 of the '286 patent;

(4) Consumers who have already purchased and obtained the ACE+7 are not enjoined from using it;

(5) Covidien shall post a bond in the amount of five million dollars ($ 5,000,000) through December 31, 2014, to cover damages suffered by Ethicon in 2014 in the event that the injunction is deemed to have been wrongfully issued;

(6) If the injunction remains in effect at the conclusion of 2014, the court will address additional security going forward;

(7) This Order shall become effective immediately upon posting of the bond.

SO ORDERED.

Dated at New Haven, Connecticut, this 22nd day of October, 2014.

/s/ Janet C. Hall
Janet C. Hall
United States District Judge

US006468286B2

(12) **United States Patent**
Mastri et al.

(10) **Patent No.: US 6,468,286 B2**
(45) **Date of Patent: Oct. 22, 2002**

(54) **ULTRASONIC CURVED BLADE**

(75) Inventors: **Dominick L. Mastri**, Bridgeport, CT (US); **Corbett W. Stone**, San Diego, CA (US)

(73) Assignee: **The United States Surgical Corporation**, Norwalk, CT (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/948,014**

(22) Filed: **Sep. 6, 2001**

(65) **Prior Publication Data**

US 2002/0019646 A1 Feb. 14, 2002

Related U.S. Application Data

(63) Continuation of application No. 09/604,877, filed on Jun. 28, 2000, now abandoned, which is a continuation of application No. 09/420,640, filed on Oct. 20, 1999, now abandoned, which is a continuation of application No. 08/911,205, filed on Aug. 14, 1997, now Pat. No. 6,024,750.

(51) **Int. Cl.**[7] **A61B 17/32**
(52) **U.S. Cl.** **606/169**; 606/174; 606/39
(58) **Field of Search** 606/1, 39–52, 606/169, 170, 171, 180, 174, 205–210, 37; 604/22; 601/2; 433/165

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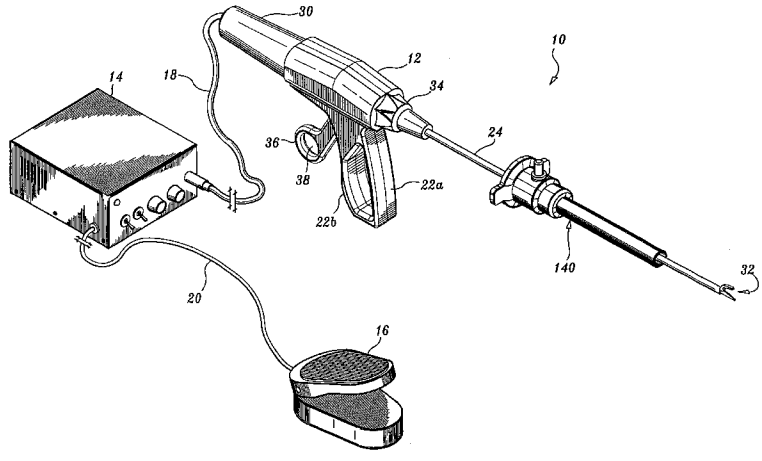
Primary Examiner—David O. Reip

(57) **ABSTRACT**

An ultrasonic dissection and coagulation system for surgical use is provided. The system includes an ultrasonic instrument, a control module, and a remote actuator. The ultrasonic instrument has a housing and an elongated body portion extending from the housing. An ultrasonic transducer supported within the housing is operatively connected to a cutting jaw by a vibration coupler. The vibration coupler conducts high frequency vibration from the ultrasonic transducer to the cutting jaw. The cutting jaw has a blade surface which is curved downwardly and outwardly in the distal direction with respect to the longitudinal axis of the elongated body portion along its length such that an angle defined by a line drawn tangent to the blade surface and the longitudinal axis of the elongated body portion varies between 5 degrees and 75 degrees. A clamp member having a tissue contact surface is positioned adjacent to the cutting jaw and is movable from an open position in which the tissue contact surface is spaced form the blade surface to a clamped position in which the tissue contact surface is in close juxtaposed alignment with the blade surface to clamp tissue therebetween. The clamp member and the curved cutting jaw combine to enhance contact between tissue and the blade surface of the cutting jaw during cutting. Further, the continuously varying angle of the blade surface with respect to the longitudinal axis of the elongated body portion facilitates selective user control over the application of force on tissue during a cutting or dissecting procedure.

20 Claims, 15 Drawing Sheets



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5,810,859	A		9/1998	DiMatteo et al.
6,024,750	A	*	2/2000	Mastri et al. 606/174

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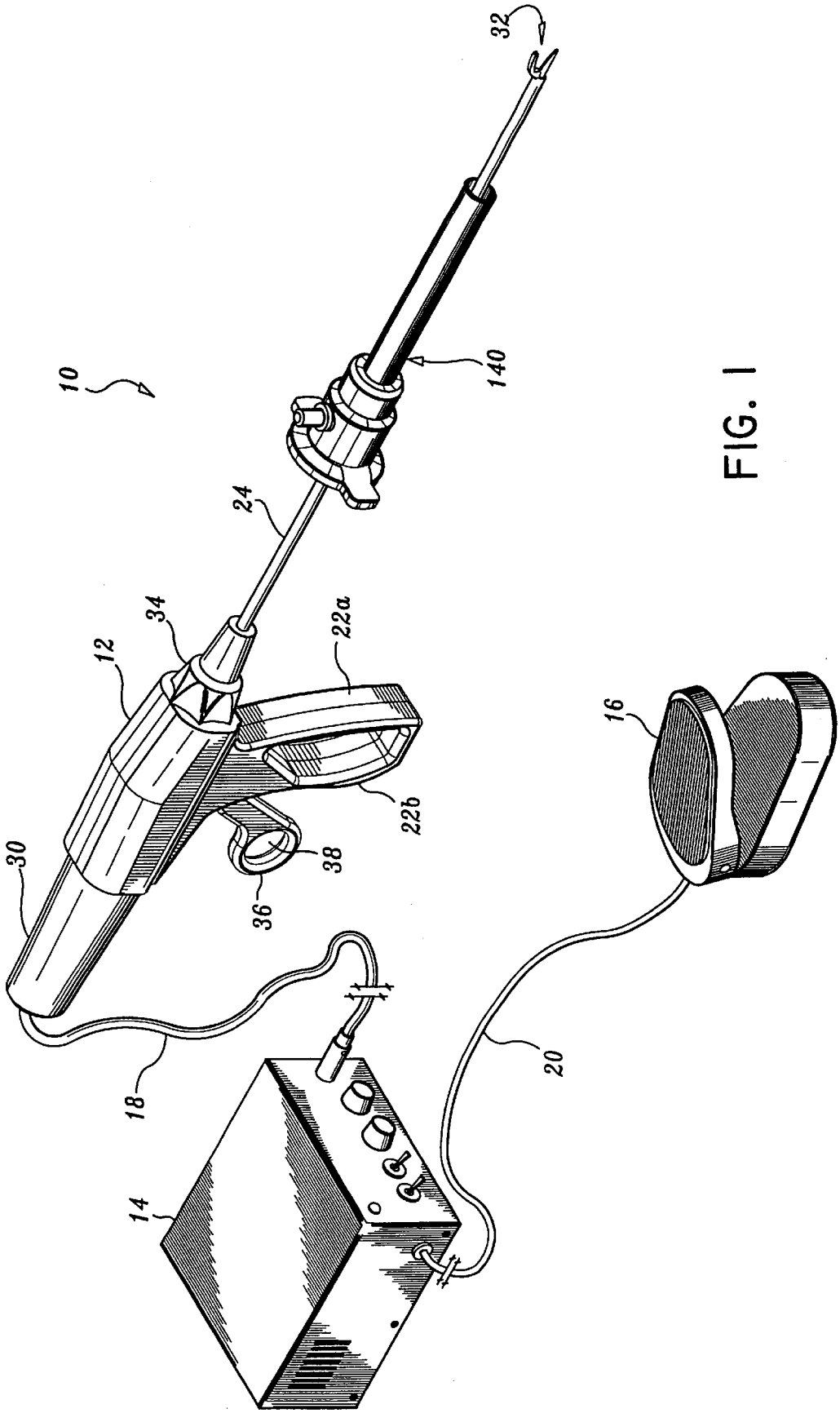


FIG. 1

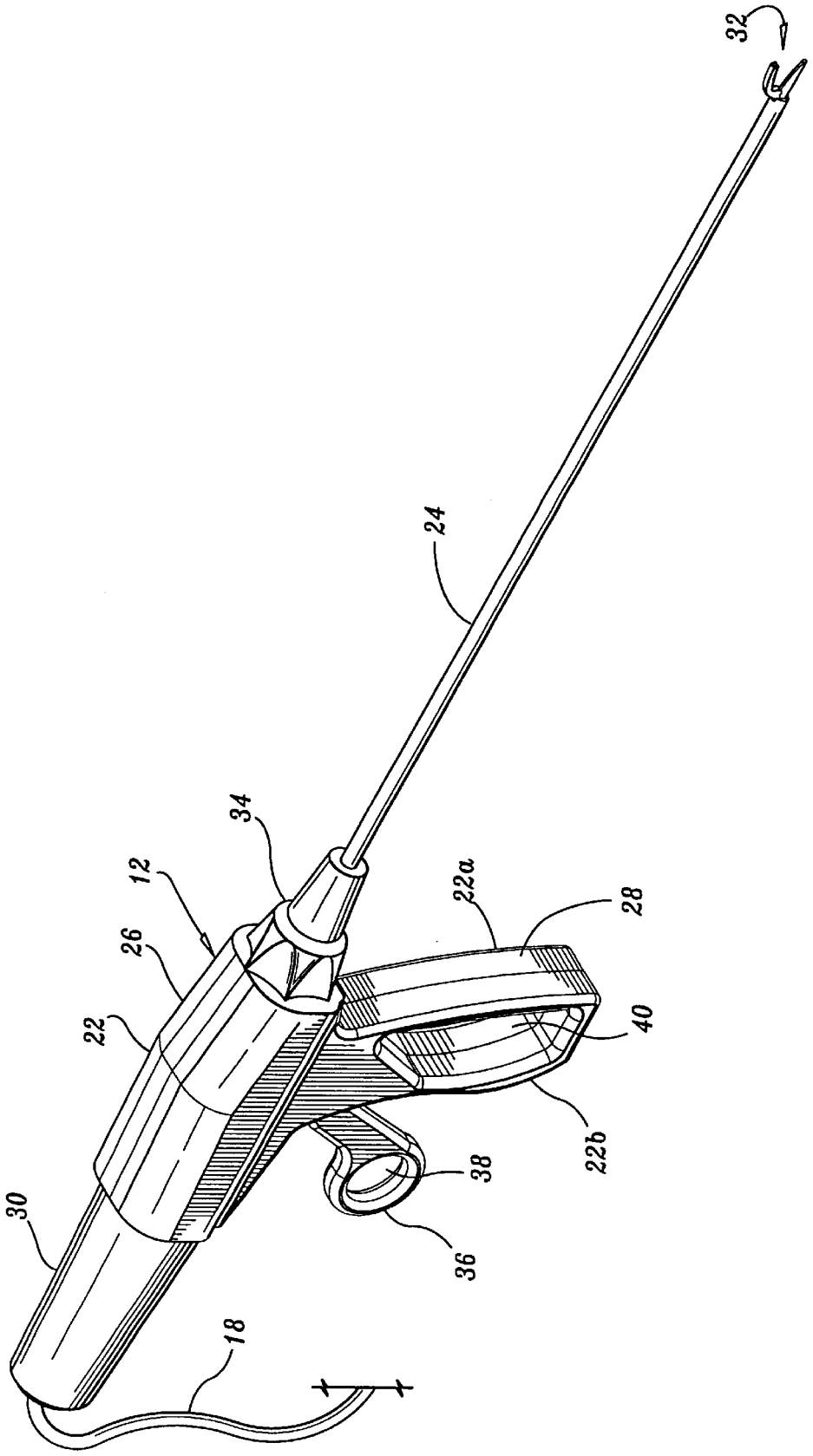


FIG. 2

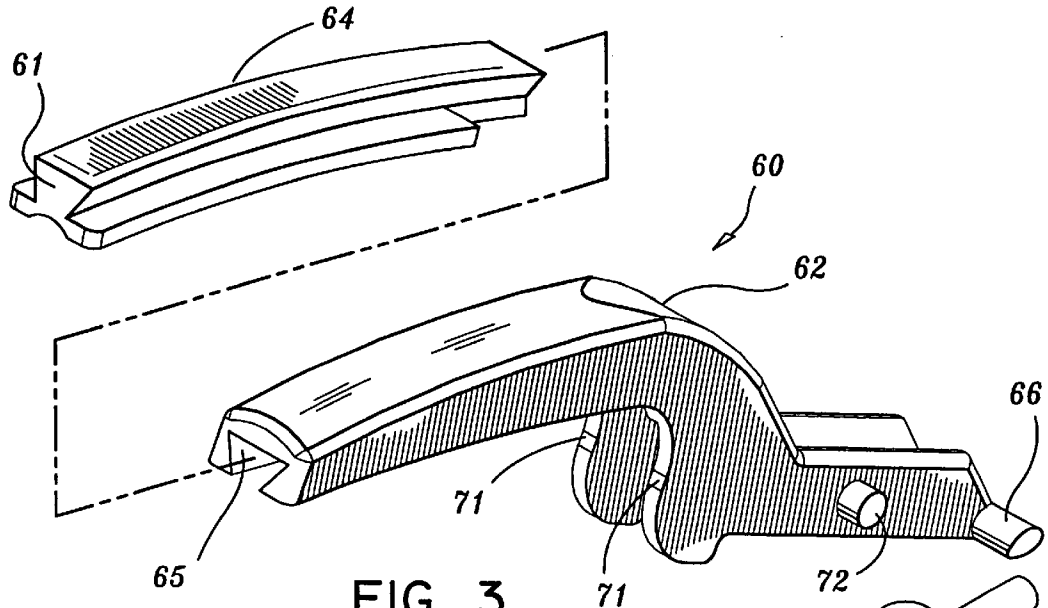

64
61
60
62
66
71
65
71
72

FIG. 3

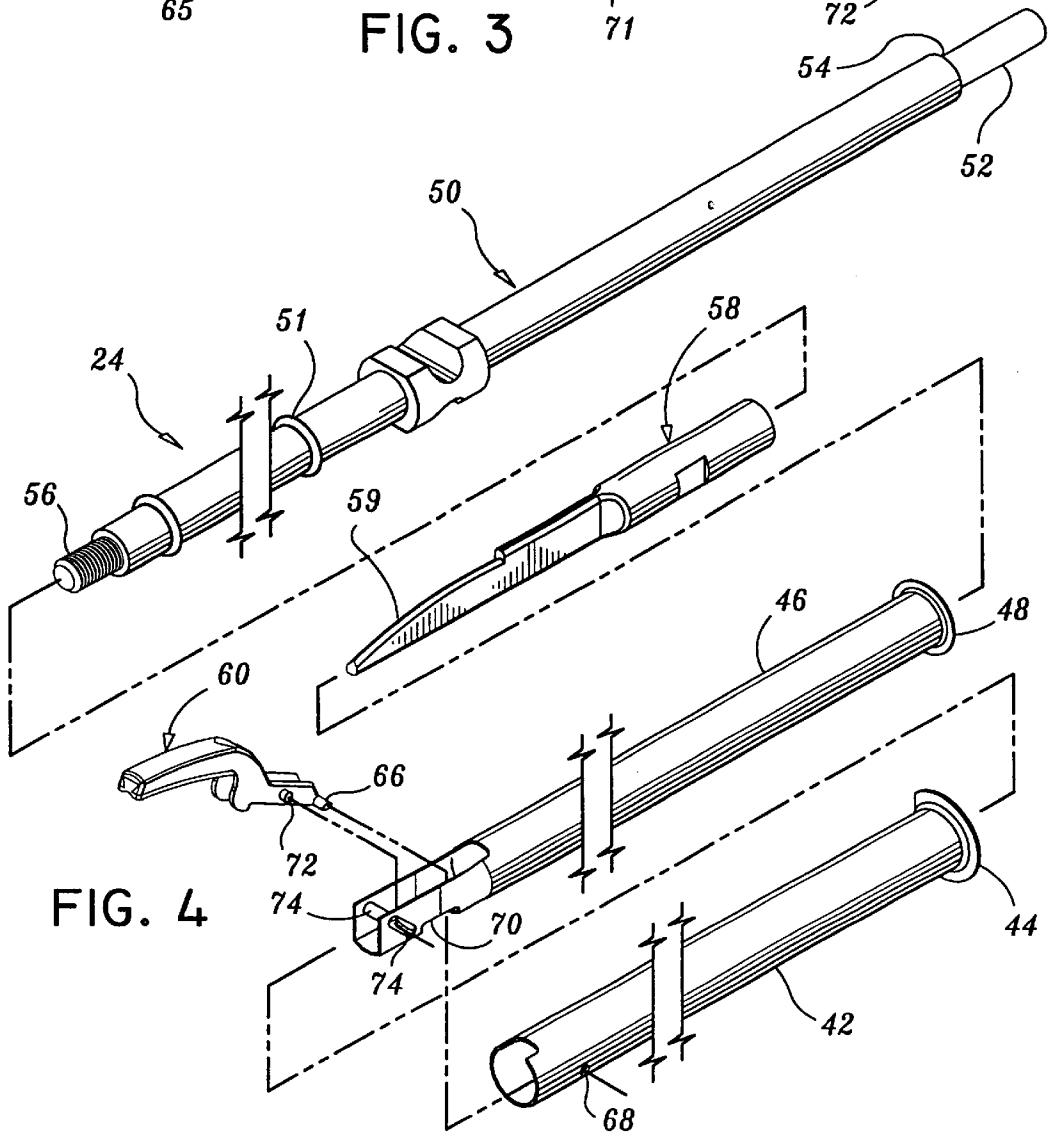

54
52
50
51
58
24
56
59
46
48
60
66
72
74
70
74
44
42
68

FIG. 4

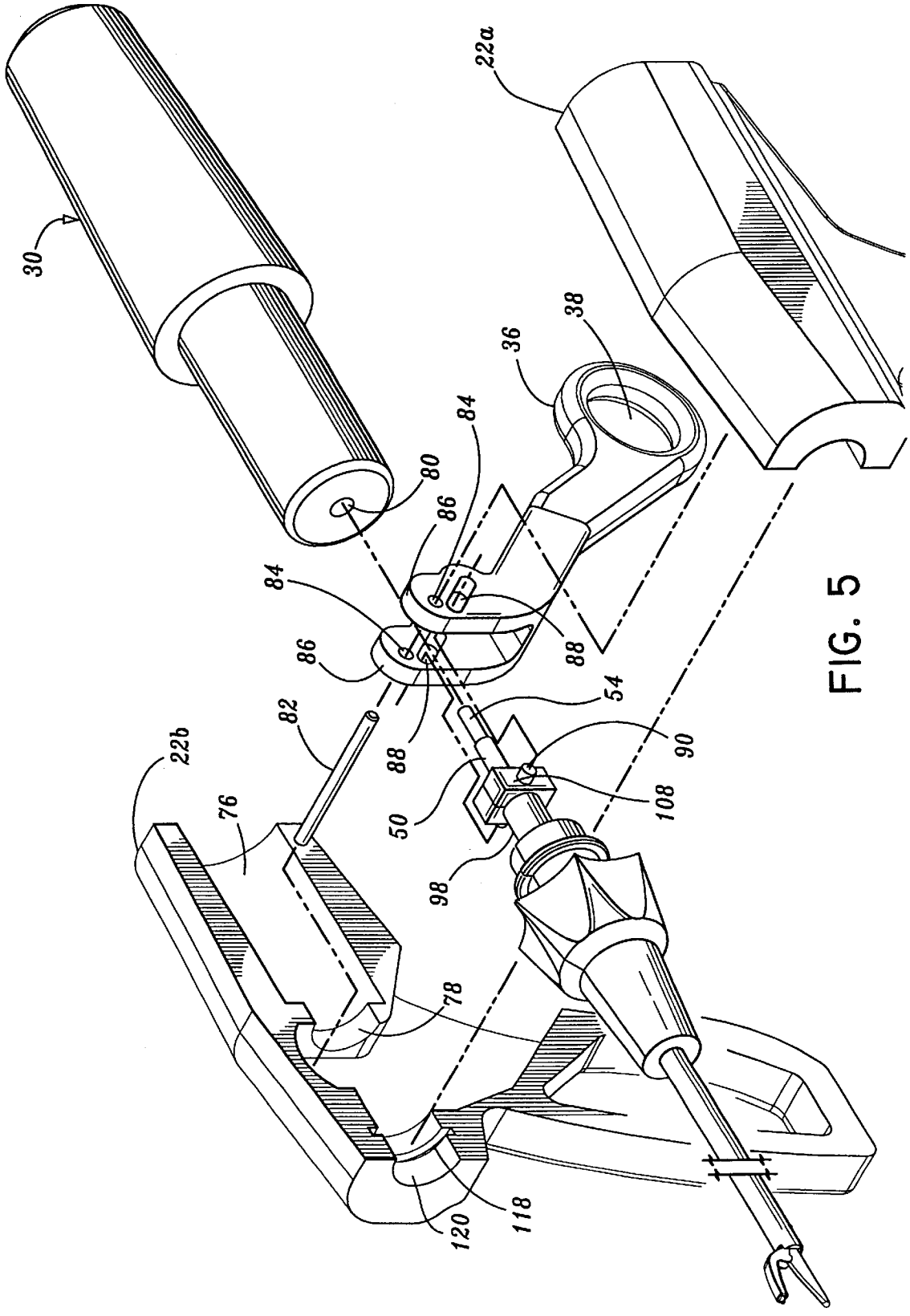


FIG. 5

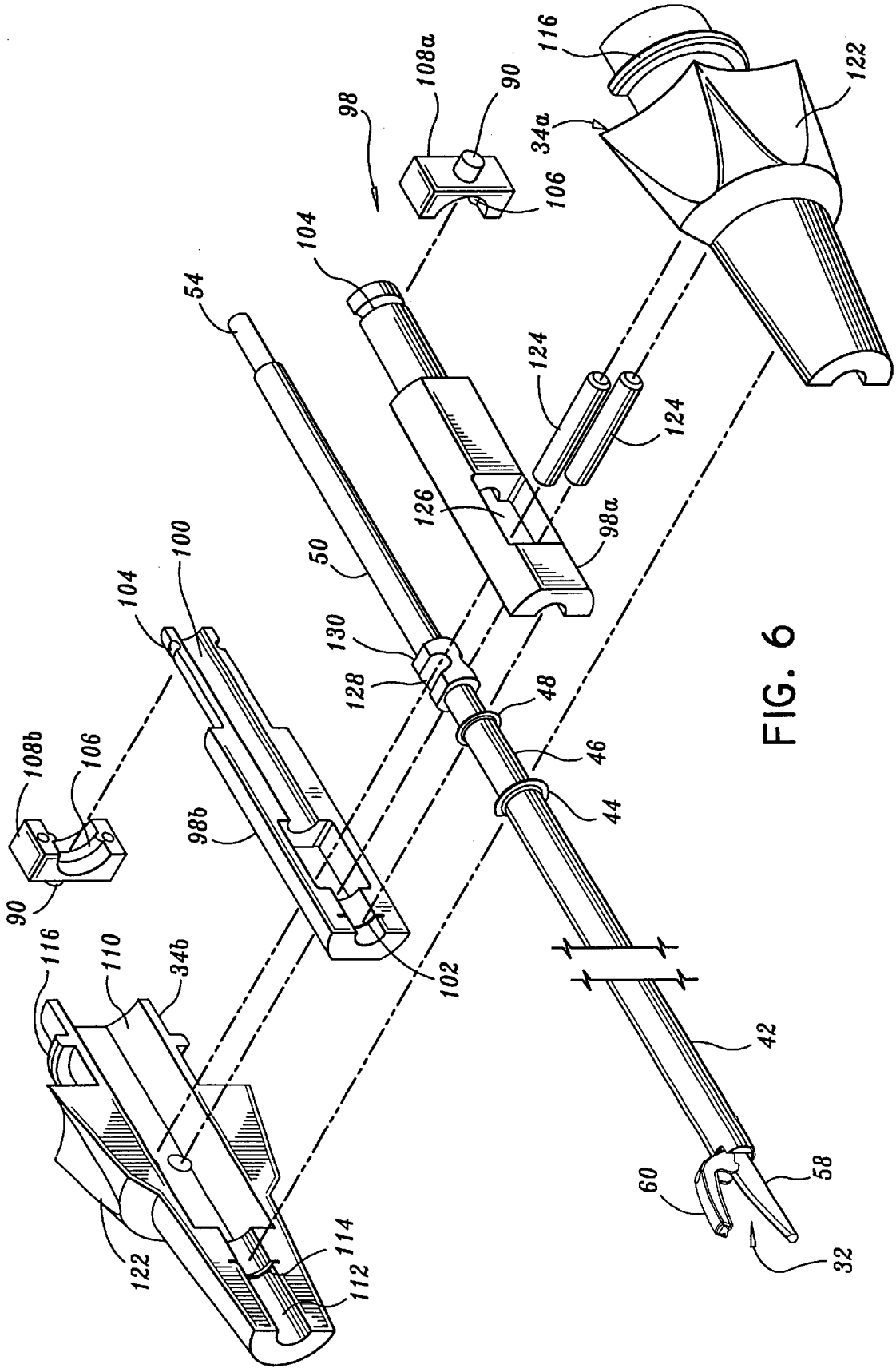

116
108a
90
98
122
34a
106
104
54
124
124
126
98a
50
100
104
130
128
48
46
44
108b
106
98b
90
116
110
34b
102
42
60
58
122
114
112
32

FIG. 6

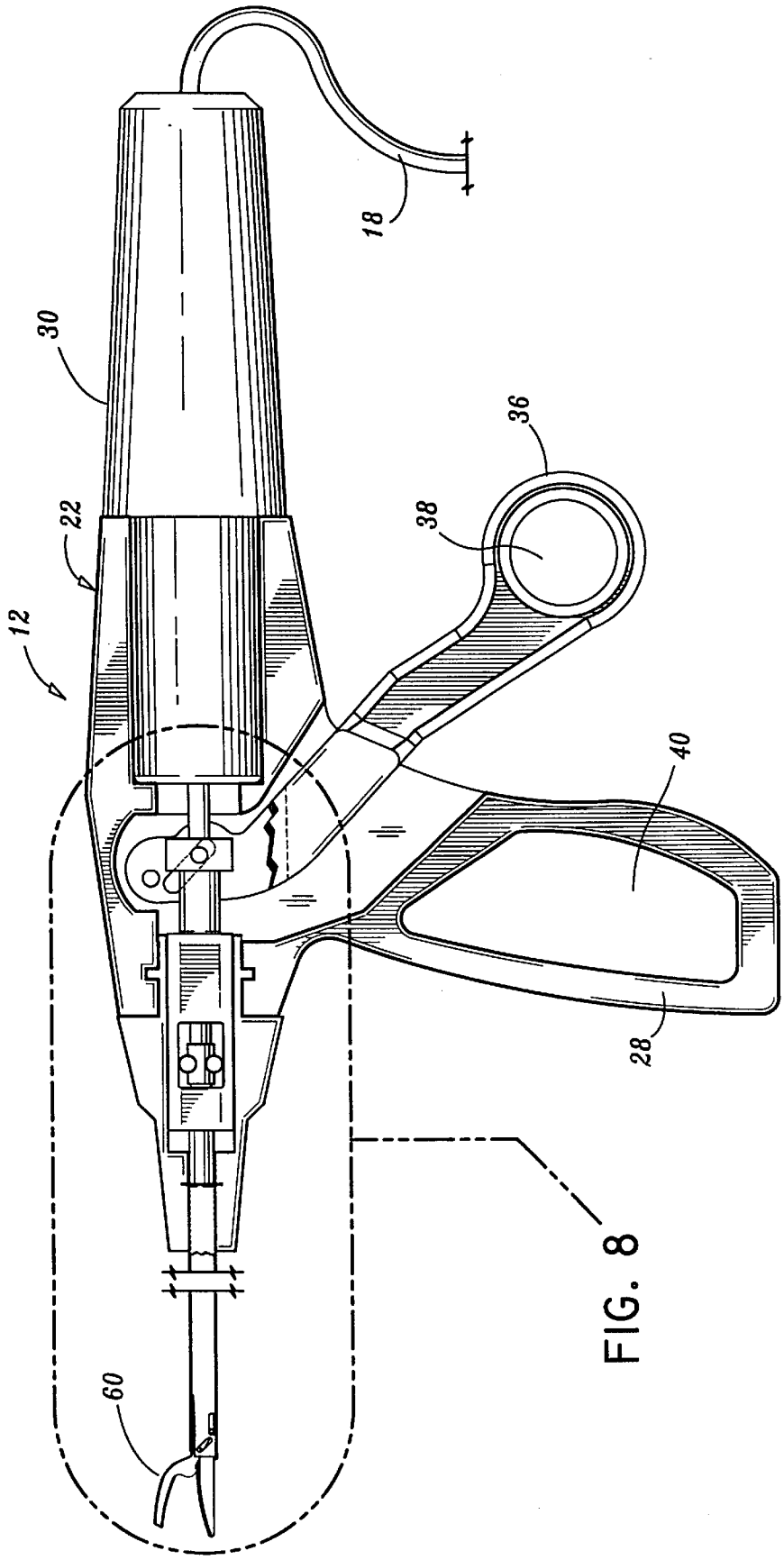


FIG. 7

FIG. 8

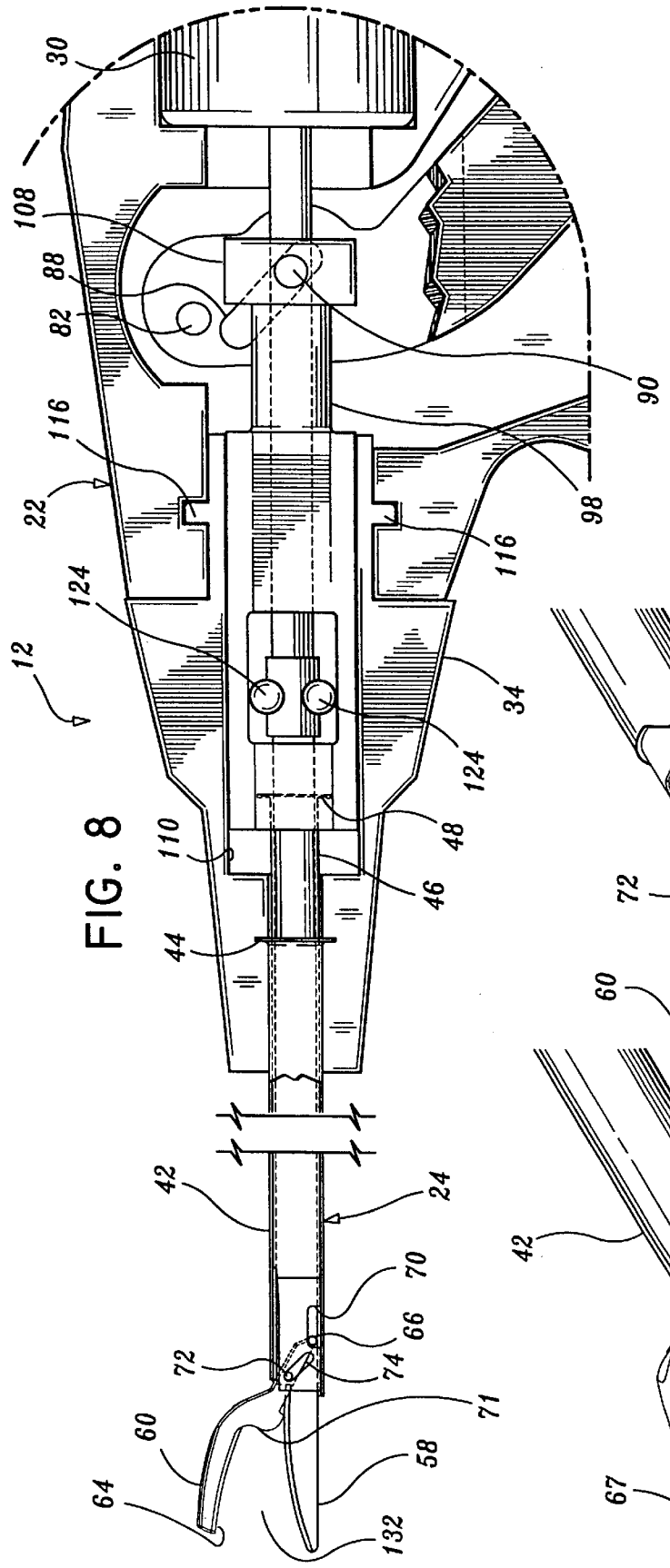


FIG. 8

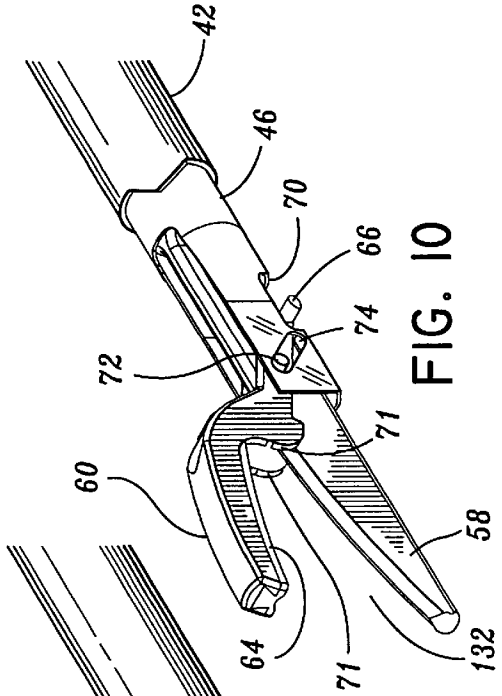


FIG. 10

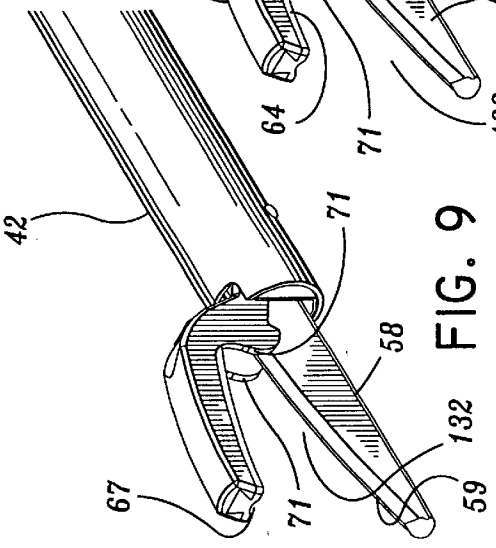
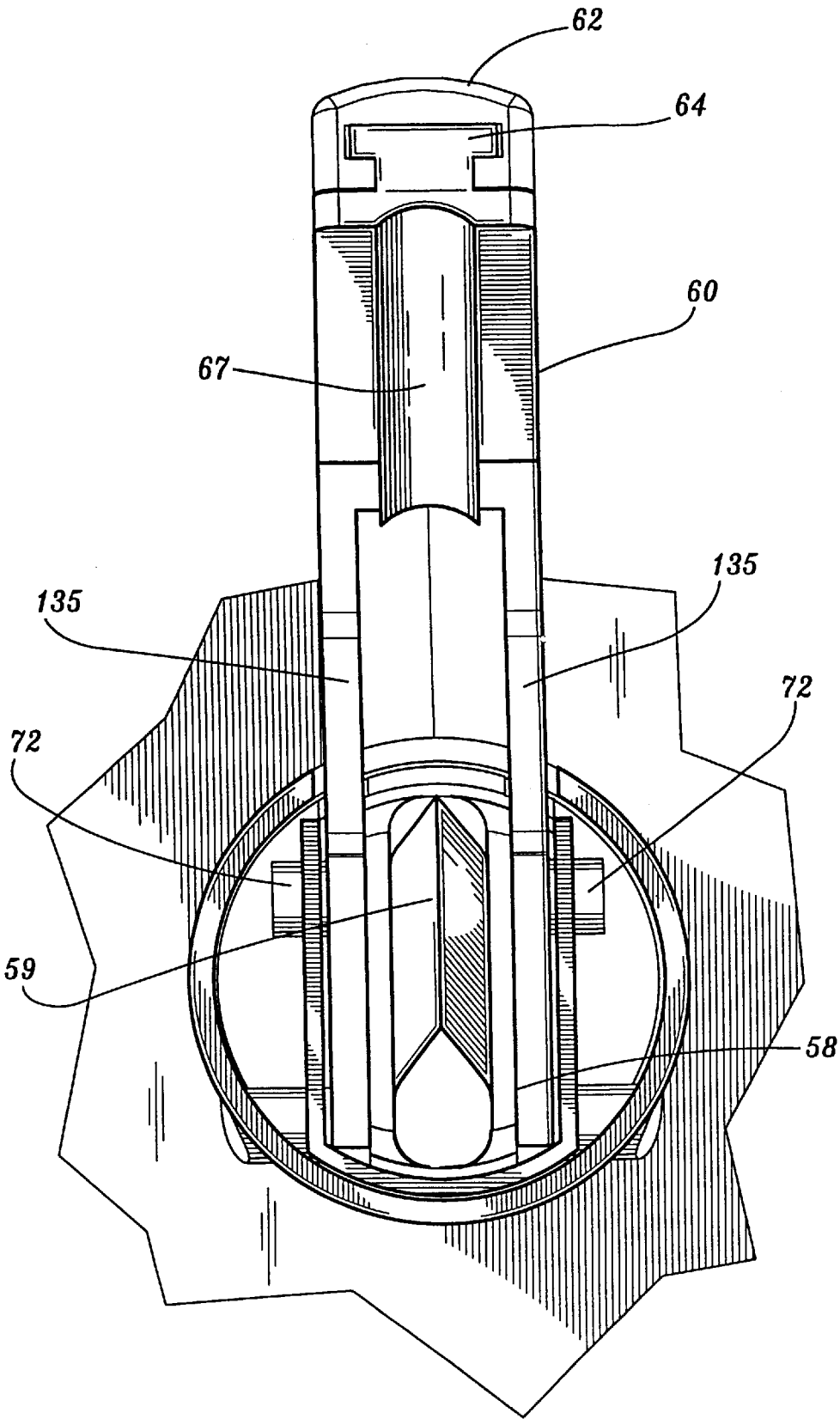


FIG. 9

FIG. 11



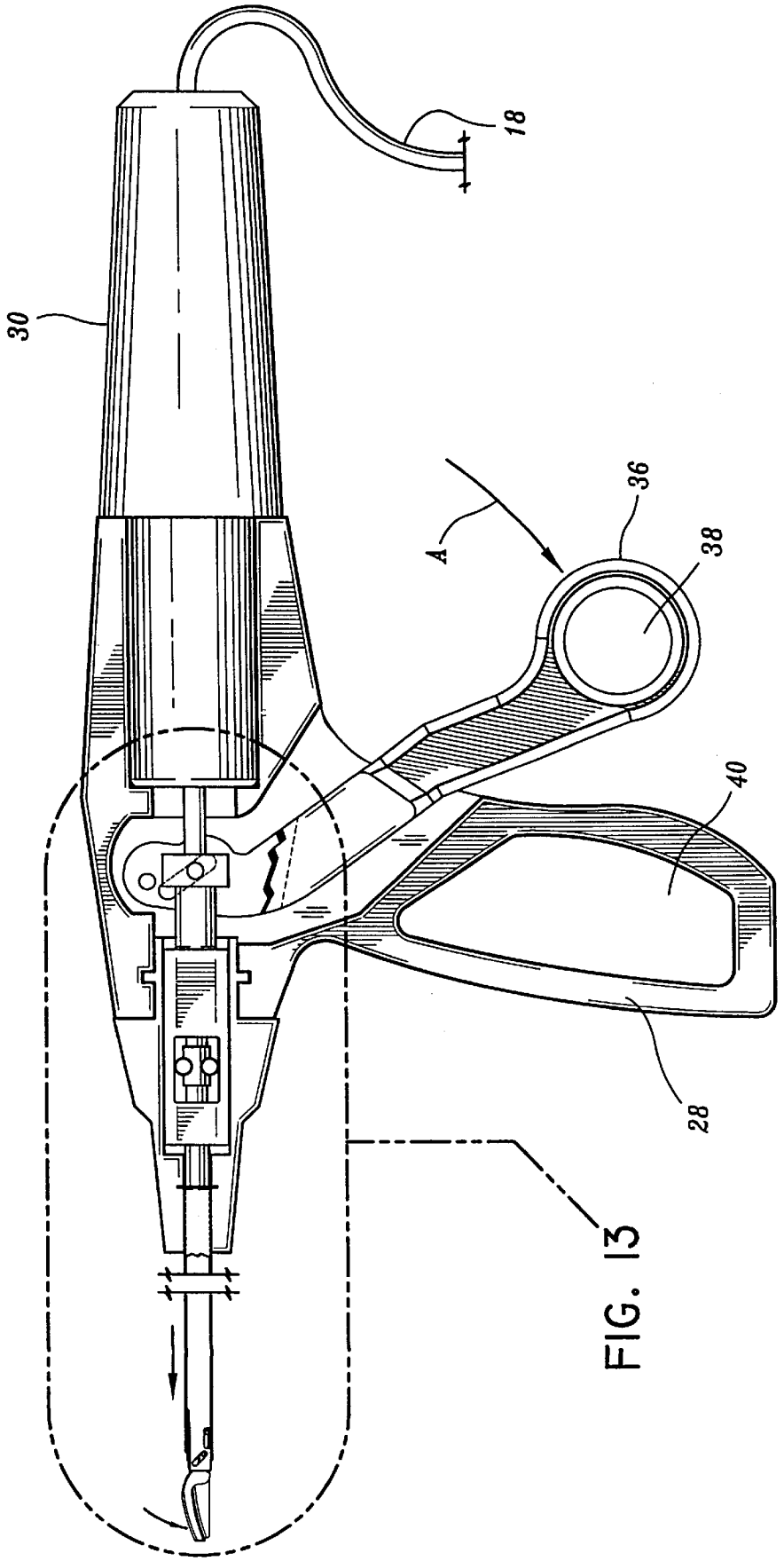


FIG. 12

FIG. 13

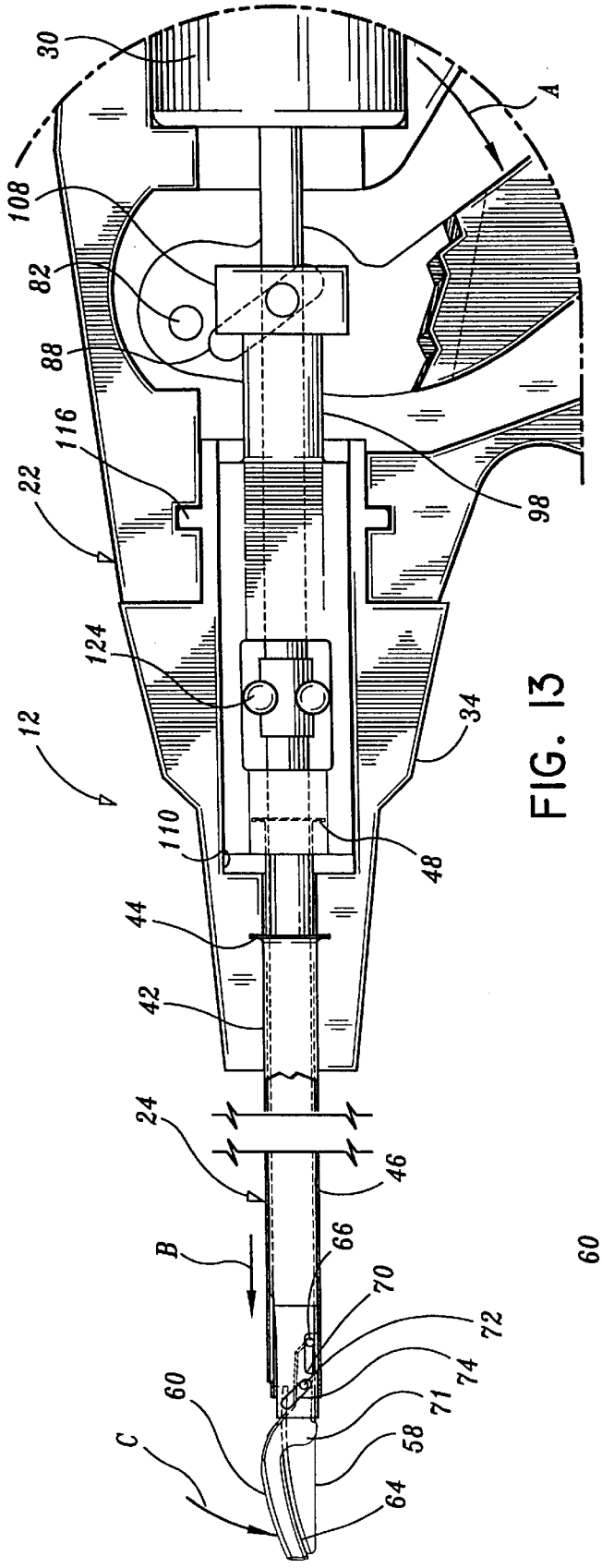

30
A
108
82
88
116
22
98
124
34
12
110
48
44
42
24
46
B
66
70
72
74
71
60
58
C
64

FIG. 13

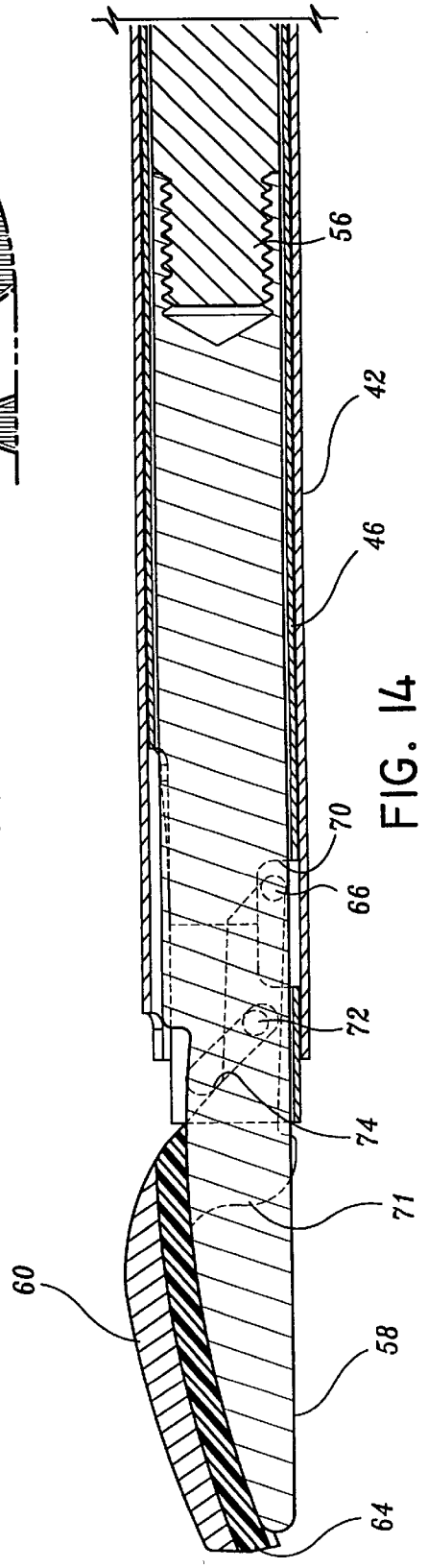

56
42
46
70
66
72
74
71
60
58
64

FIG. 14

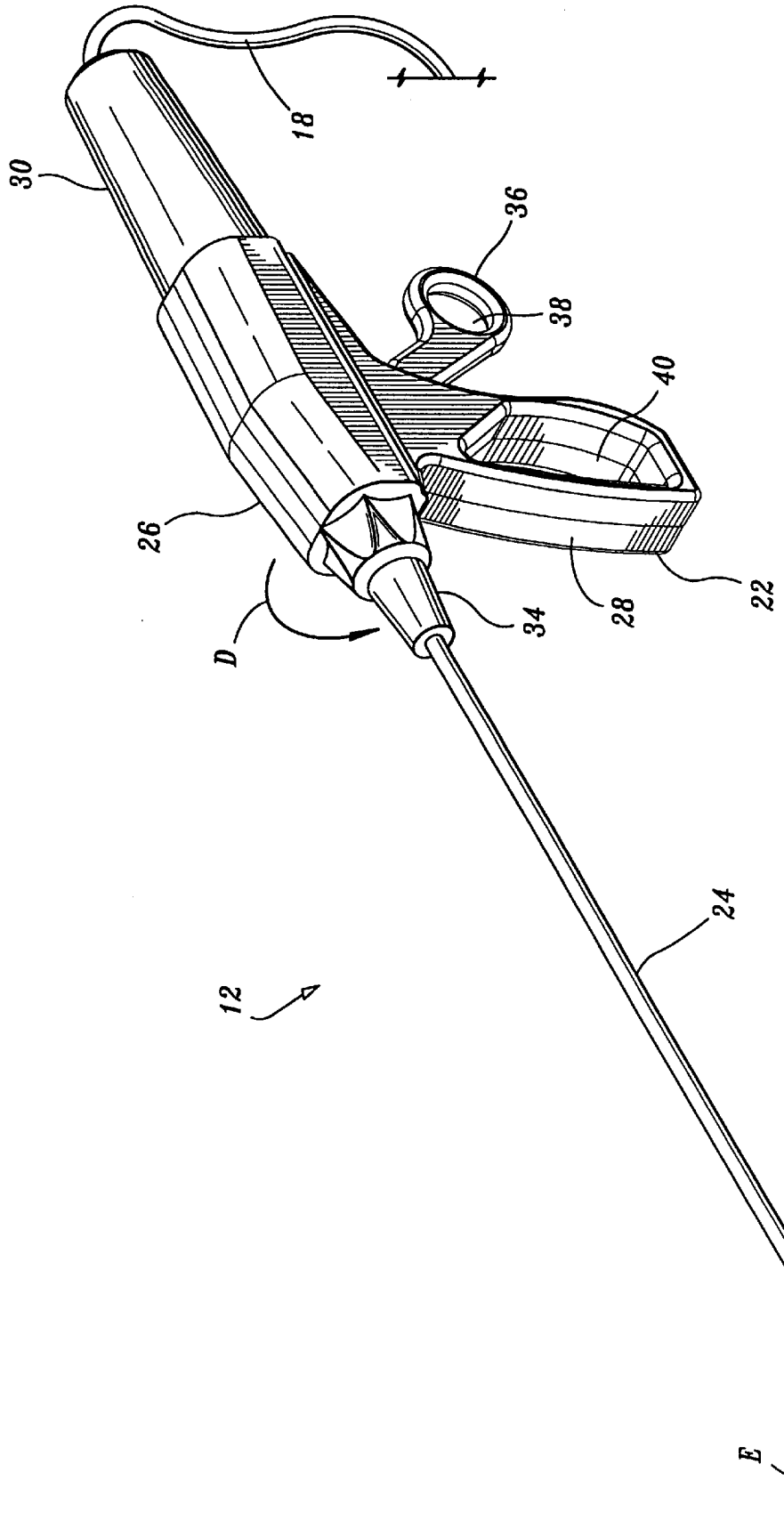


FIG. 15

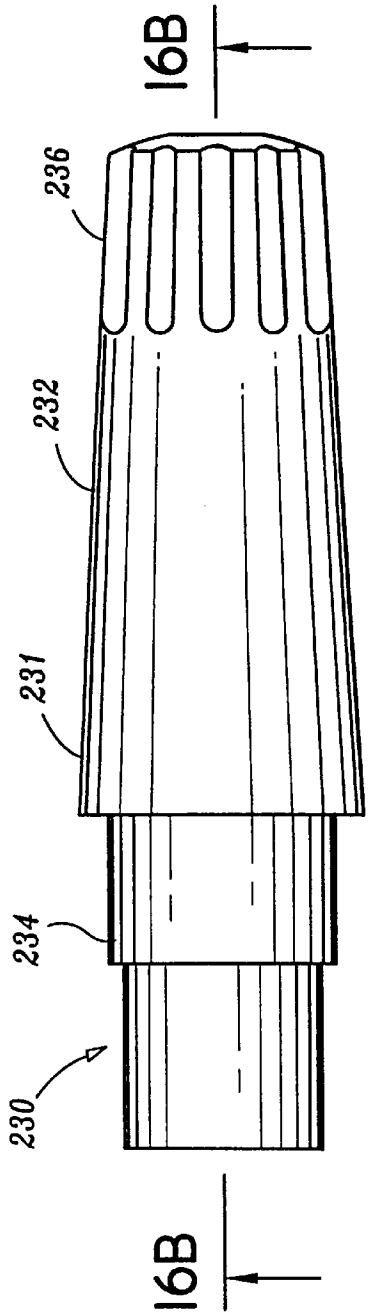


FIG. 16A

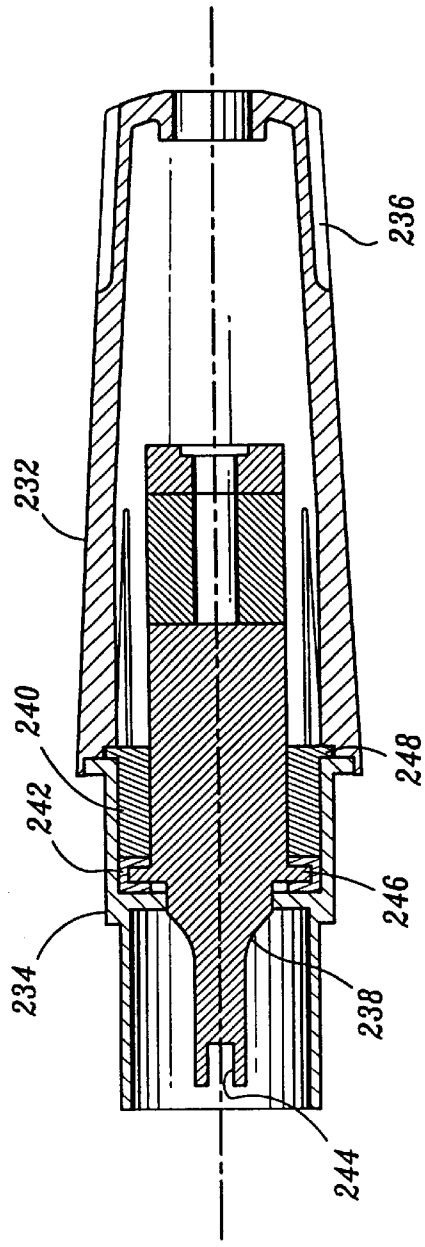


FIG. 16B

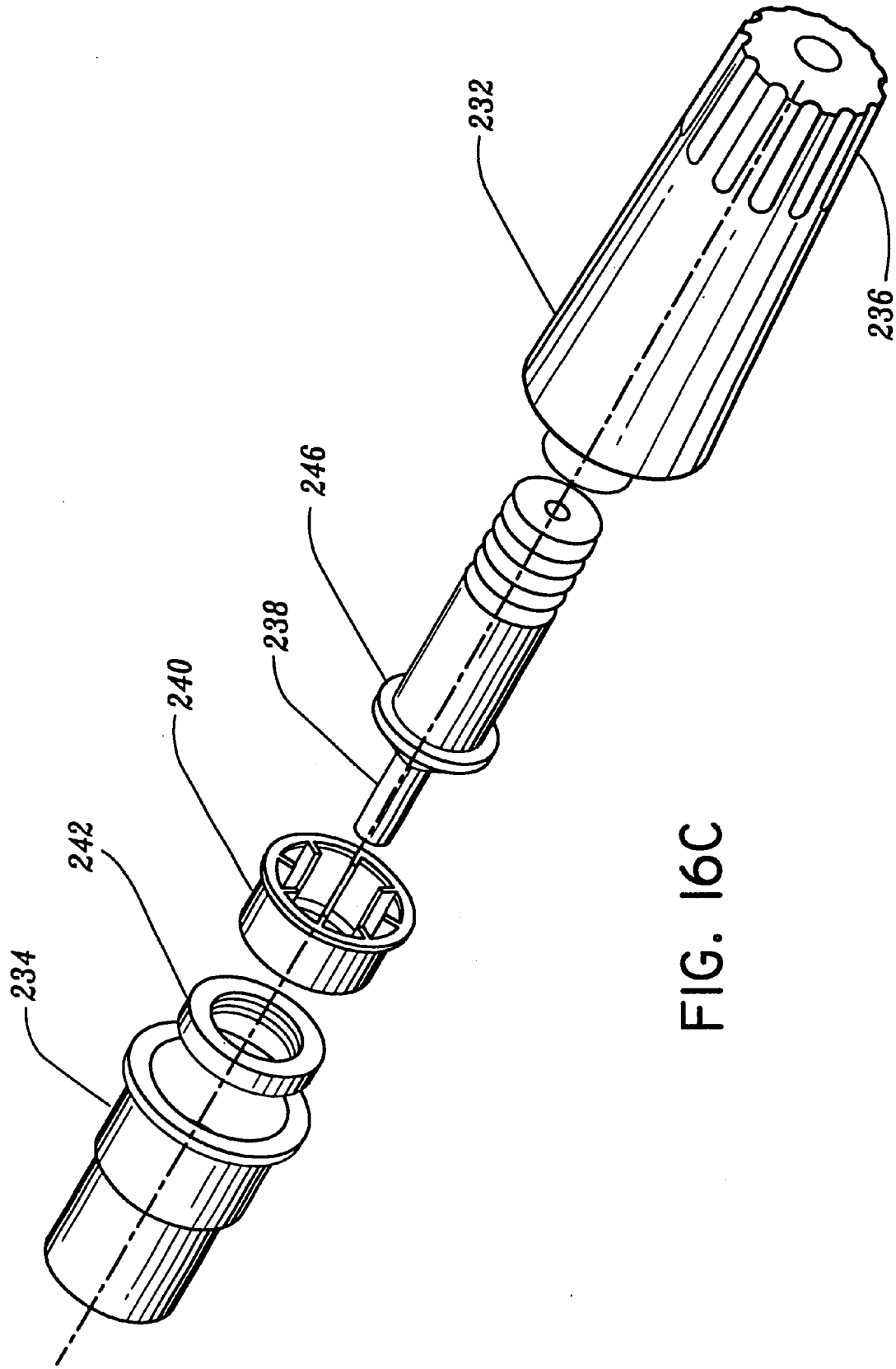


FIG. 16C

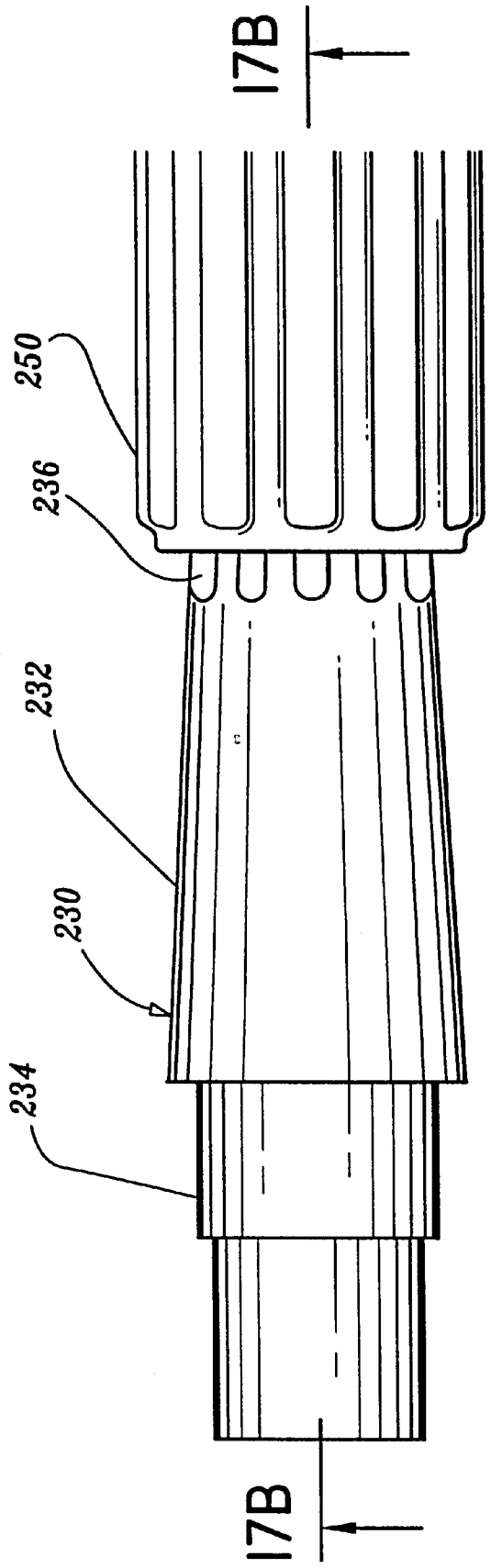


FIG. 17A

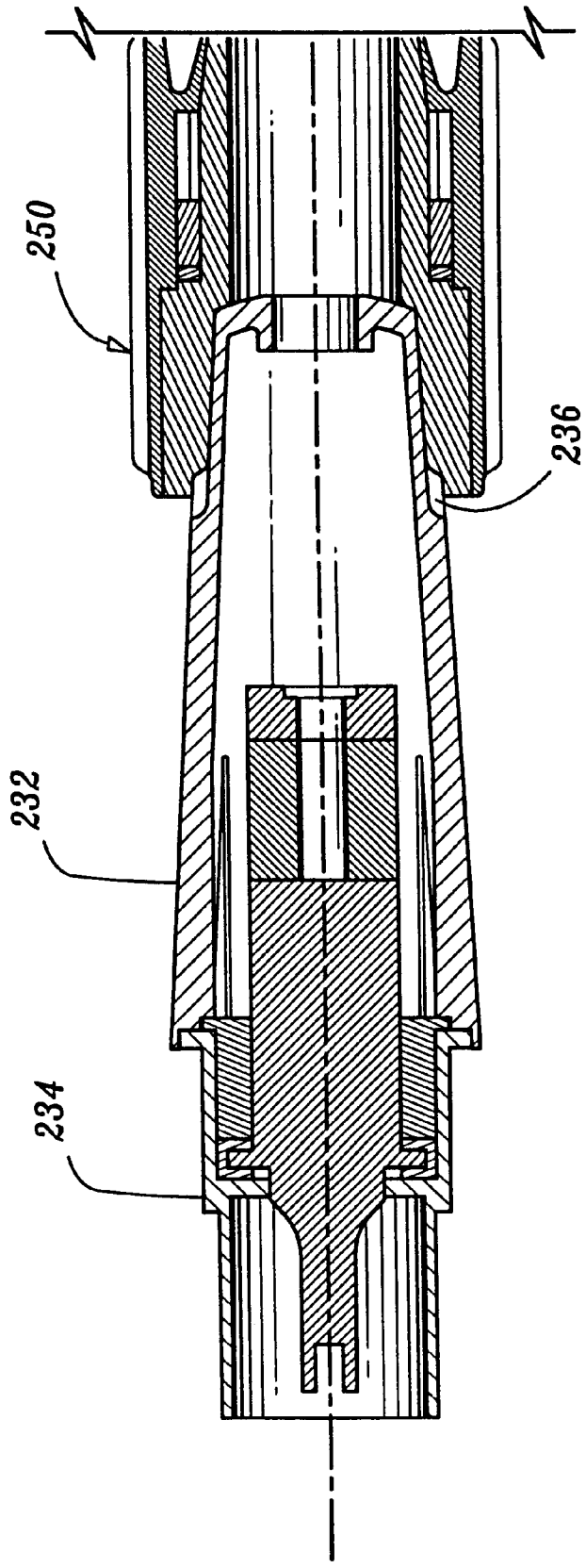


FIG. 17B

ULTRASONIC CURVED BLADE

CROSS REFERENCE TO RELATED APPLICATION

This application is a continuation of U.S. patent application Serial No. 09/604,877, filed Jun. 28, 2000, now abandoned which is a continuation of Ser. No. 09/420,640, filed Oct. 20, 1999, now abandoned which is a continuation of Ser. No. 08/911,205, filed Aug. 14, 1997, now U.S. Pat. No. 6,024,750, all of which are incorporated herein by reference.

BACKGROUND

1. Technical Field

The present disclosure relates to an ultrasonic dissection and coagulation system for surgical use. More specifically, the present disclosure relates to an ultrasonic instrument including a curved blade and a clamp member particularly suited for performing dissection and coagulation of tissue.

2. Background of Related Art

Ultrasonic instruments for surgical use and the benefits associated therewith are well known. For example, the use of an ultrasonic generator in conjunction with a surgical scalpel facilitates faster and easier cutting of organic tissue and accelerates blood vessel clotting in the area of the cut, i.e., accelerated coagulation. Improved cutting results from increased body tissue to scalpel contact caused by the high frequency of vibration of the scalpel blade with respect to body tissue. Improved coagulation results from heat generated by contact between the scalpel blade and the body tissue as the scalpel blade is vibrated at a high frequency. Thus, in order to reap the advantages associated with ultrasonic energy, good blade to tissue contact is important.

U.S. Pat. No. 3,862,630 ("Balamuth") discloses an ultrasonic system including an ultrasonic motor, a tool member having a working surface oriented normal to the direction of mechanical vibration generated by the ultrasonic motor, and a clamp member extending parallel to the tool member for compressing tissue against the tool member. U.S. Pat. No,. 5,322,055 ("Davison") discloses an ultrasonic surgical instrument adapted for endoscopic use having a blade and a clamp movable in relation to the blade to capture tissue therebetween. The blade and the clamp define a clamping region having a plane which is parallel to the longitudinal axis of the surgical instrument. During an endoscopic procedure, movement of the instrument is limited to movement along an axis parallel to the plane of the clamping region. Thus, no additional blade force is imposed on the body tissue as a result of movement of the instrument.

Accordingly, a need exists for an improved ultrasonic surgical instrument which is easy to use and provides fast and easy cutting and improved coagulation.

SUMMARY

In accordance with the present disclosure, an ultrasonic system for dissection and coagulation of tissue is provided. The system includes an ultrasonic instrument, a control module, and a remote actuator. The ultrasonic instrument has a housing and an elongated body portion extending from the housing. An ultrasonic transducer supported within the housing is operatively connected to a cutting jaw by a vibration coupler. The vibration coupler conducts high frequency vibration from the ultrasonic transducer to the cutting jaw. The cutting jaw has a blade surface which is curved outwardly and downwardly along its surface and thus, curved with respect to the axis of vibration. The curved blade surface is preferably configured such that the angle defined between a line tangent to the blade surface and the longitudinal axis of the elongated body portion varies from about 5 degrees to about 45 degrees along the length of the blade surface. A clamp member having a tissue contact surface is positioned adjacent to the cutting jaw and is movable from an open position in which the tissue contact surface is spaced from the blade surface to a clamped position in which the tissue contact surface is in close juxtaposed alignment with the blade surface to clamp tissue therebetween. The clamp member and the angled blade combine to enhance contact between tissue and the blade surface of the blade member.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a perspective view of the ultrasonic dissection and coagulation system with the ultrasonic instrument inserted partially through a cannula;

FIG. **2** is a perspective view of the ultrasonic instrument of FIG. **1**;

FIG. **3** is a perspective view with parts separated of the clamp of the ultrasonic instrument of FIG. **1**;

FIG. **4** is a perspective view with parts separated of the elongated body portion of the ultrasonic instrument of FIG. **1**;

FIG. **5** is a perspective view with parts separated of the ultrasonic instrument of FIG. **1**;

FIG. **6** is a perspective view with parts separated of the rotation assembly of the ultrasonic instrument of FIG. **1**;

FIG. **7** is a side partial cutaway view of the ultrasonic instrument of FIG. **1** in the open position;

FIG. **8** is an enlarged view of the indicated area of detail of FIG. **7** illustrating the clamp in the open position;

FIG. **9** is a perspective view of the distal end of the elongated body portion of the ultrasonic instrument of FIG. **1** with the clamp in the open position;

FIG. **10** is a perspective partial cutaway view of the distal end of the elongated body portion of the ultrasonic instrument of FIG. **1** with the clamp in the open position;

FIG. **11** is a front perspective, partial cutaway view of the distal end of the elongated body portion of the ultrasonic instrument of FIG. **1** with the clamp in the open position;

FIG. **12** is a side partial cutaway view of the ultrasonic instrument of FIG. **1** with the clamp in the clamped (closed) position;

FIG. **13** is an enlarged view of the indicated area of detail of FIG. **12** illustrating the clamp in the closed position;

FIG. **14** is a side cross-sectional view of the distal end of the elongated body portion of the ultrasonic instrument of FIG. **1** in the clamped position;

FIG. **15** is a perspective view of the ultrasonic instrument of FIG. **1** with the elongated body portion partially rotated;

FIG. **16**A is a side view of an alternate embodiment of the ultrasonic transducer of FIG. **1**;

FIG. **16**B is a side cross-sectional view taken along section line **16**B—**16**B of FIG. **16**A.

FIG. **16**C is a perspective view with parts separated of the ultrasonic transducer of FIG. **16**A;

FIG. **17**A is a side view of a torque wrench assembly in engagement with the ultrasonic transducer of FIG. **16**A; and

FIG. **17**B is a side cross-sectional view taken along section line **17**B—**17**B of FIG. **17**A.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Preferred embodiments of the presently disclosed ultrasonic dissection and coagulation system will now be

described in detail with reference to the drawings, in which like reference numerals designate identical or corresponding elements in each of the several views.

FIG. **1** illustrates the ultrasonic dissection and coagulation system shown generally as **10**. Briefly, dissection and coagulation system **10** includes ultrasonic instrument **12**, control module **14**, and remote actuator **16**. Control module **14** is operatively connected to ultrasonic instrument **12** by electrically conductive cable **18** and functions to control the power and frequency of current supplied to ultrasonic instrument **12**. Any suitable controller capable of delivering power to ultrasonic instrument **12** can be used. Control module **14** does not form part of the invention and will not be further discussed herein. Remote actuator **16**, e.g., pedal actuator, is operatively connected to control module **14** by electrically conductive cable **20** and can be actuated to initiate the supply of power to ultrasonic instrument **12** via control module **14** to effect vibratory motion of ultrasonic instrument **12** to cut and coagulate tissue.

As illustrated in FIG. **2**, ultrasonic instrument **12** includes housing **22** and elongated body portion **24** extending distally therefrom. Housing **22** is preferably formed from molded housing half-sections **22***a* and **22***b* and includes a barrel portion **26** having a longitudinal axis aligned with the longitudinal axis of body portion **24** and a stationary handle portion **28** extending obliquely from barrel portion **26**. Ultrasonic transducer **30** is supported within and extends from the proximal end of housing **22** and is connected to control module **14** via cable **18**. Jaw assembly **32** is disposed adjacent the distal end of elongated body portion **24** and is actuated by moving movable handle **36** with respect to stationary handle portion **28**. Movable handle **36** and stationary handle portion **28** include openings **38** and **40**, respectively, to facilitate gripping and actuation of ultrasonic instrument **12**. Elongated body portion **24** is supported within rotatable knob **34** and may be selectively rotated by rotating knob **34** with respect to housing **22** to change the orientation of jaw assembly **32**.

FIGS. **3** and **4** illustrate elongated body portion **24** with parts separated. Elongated body portion **24** includes an outer tube **42** which is preferably cylindrical and has a proximally located annular flange **44** dimensioned to engage rotatable knob **34** (FIG. **2**) as described below. An elongated actuator tube **46**, which is also preferably cylindrical, is configured to be slidably received within outer tube **42** and includes a proximally located annular flange **48** dimensioned to engage coupling member **98** (FIG. **5**) which is supported within housing **22** (FIG. **2**) and will be described in detail below. Vibration coupler **50** is dimensioned to extend through elongated actuator tube **46** and includes a proximal end **52** having a reduced diameter portion **54** configured to operatively engage ultrasonic transducer **30** (FIG. **5**) and a distal end **56** adapted to be operatively connected to cutting jaw **58**. A plurality of silicon rings **51** can be molded or otherwise attached to the nodal points along vibration coupler **50** to seal between vibration coupler **50** and actuator tube **46**. Preferably, cutting jaw **58** includes an internal proximal threaded bore (not shown) which is dimensioned to receive threaded distal end **56** of vibration coupler **50**. Alternately, cutting jaw **58** can be formed integrally with vibration coupler **50**, cutting jaw **58** may include a threaded proximal end configured to be received within a threaded bore formed in vibration coupler **50**, or other attachment devices can be used. A clamp **60** having a clamp body **62** and a tissue contact member **64** removably secured to clamp body **62** is operatively connected to the distal end of actuator tube **46**. Clamp body **62** includes a pair of tissue receiving stops **71** that define the proximal end of the exposed blade surface **59**. Tissue contact member **64** is preferably composed of teflon and is preferably removably fastened to clamp body **62** by a tongue and groove fastening assembly (reference numerals **61** and **65**, respectively), although other fastening assemblies are also envisioned. Tissue contact member **64** functions to isolate clamp **60**, which is preferably metallic, from jaw **58** which is also preferably metallic to prevent metal to metal contact.

Tissue contact member **50** also functions to grip tissue to prevent movement of the tissue with vibrating cutting jaw **58**. Alternately, at least one row of teeth may be positioned on clamp **60** to grip tissue, such as disclosed in U.S. patent application Ser. No. 08/911,207, which is incorporated herein by reference. Pivot members (pins) **66** located at the proximal end of clamp body **62** are configured to be received within openings **68** formed in the distal end of outer tube **42**. A guide slot **70** formed in the distal end of actuator tube **46** permits relative movement between actuator tube **46** and clamp body **62** by allowing pins **66** to move in guide slot **70**. A pair of camming members **72** are also formed on clamp body **62** and are positioned to be received within cam slots **74** formed in the distal end of actuator tube **46**. Movement of actuator tube **46** and clamp **60** will be described in detail below.

Cutting jaw **58** includes a curved blade surface **59** that slopes downwardly and outwardly in the distal direction. Preferably, the entire blade surface **59** exposed to tissue, i.e., the portion of blade surface **59** between tissue receiving stops **71** and the distal end of blade surface **59**, has a tangent which defines an angle with respect to the longitudinal axis of elongated body portion **24** that varies along the length of blade surface **59** from about 5 degrees to about 75 degrees. Ideally, the angle defined by a line tangent to the blade surface and the longitudinal axis of elongated body portion **24** varies from about 5 degrees to about 45 degrees along the length of the blade surface. The curved blade surface provides better visibility at the surgical site. Clamp **60** is movable from an open position in which tissue contact member **64** is spaced apart from blade surface **59** (FIGS. **7** and **8**) to a clamped position in which tissue contact member is in juxtaposed close alignment with blade surface **59** (FIGS. **11–13**) to clamp tissue therebetween. The interior surface of tissue contact member **64** is curved to correspond to blade surface **59**. In the clamped position, note the positioning of tissue contact member **64** with respect to blade surface **59**. Actuation of clamp **60** from the open position to the clamped position will be described in detail below.

Referring now to FIGS. **5** and **6**, the handle assembly and the rotation assembly will now be discussed. Housing half-sections **22***a* and **22***b* define a chamber **76** configured to receive a portion of ultrasonic transducer **30**. Chamber **76** has an opening **78** communicating with the interior of housing **22**. Ultrasonic transducer **30** includes a bore **80** configured to receive proximal end **54** of vibration coupler **50**. In the assembled condition, proximal end **54** extends through opening **78** into bore **80**. Ultrasonic transducer **30** may be secured within housing **22** to vibration coupler **50** using any known attachment apparatus. Preferably, a torque wrench, such as disclosed in copending U.S. patent application Ser. No. 08/911,207, now U.S. Pat. No. 6,036,667, incorporated herein by reference above, can be used to secure ultrasonic transducer **30** to vibration coupler **50**. As disclosed therein, the proximal end of transducer **30** may be configured to engage the torque wrench. Movable handle **36** is pivotally connected between housing half-sections **22***a*

and 22*b* about pivot pin **82** which extends through holes **84** formed in legs **86** of movable handle **36**. A cam slot **88** formed in each leg **86** is configured to receive a protrusion **90** projecting outwardly from coupling member **98** (FIG. **6**).

As illustrated in FIG. **6**, coupling member **98** operatively connects movable handle **36** to actuator tube **46** and is preferably formed from molded half-sections **98***a* and **98***b* to define a throughbore **100** dimensioned to slidably receive the proximal end of vibration coupler **50**. Coupling member **98** has an inner distally located annular groove **102** dimensioned to receive annular flange **48** of actuator tube **46** and an outer proximally located annular groove **104**. Groove **104** is positioned to receive an annular rib **106** formed on the internal wall of a swivel member **108** (FIG. **5**). Swivel member **108** is preferably formed from molded half-sections **108***a* and **108***b* and permits rotation of coupling member **98** relative to movable handle **36**. Protrusions **90** project outwardly from sidewalls of swivel member **108** and extend through cam slots **88** of movable handle **36** (FIG. **5**).

Referring to FIGS. **5** and **6**, rotation knob **34** is preferably formed from molded half-sections **34***a* and **34***b* and includes a proximal cavity **110** for slidably supporting coupling member **98** and a distal bore **112** dimensioned to receive outer tube **42**. An annular groove **114** formed in bore **112** is positioned to receive annular flange **44** of outer tube **42**. The outer wall of knob **34** has a proximally located annular ring **116** dimensioned to be rotatably received within annular slot **118** formed in opening **120** of housing **22**. The outer wall of knob **34** also includes scalloped surface **122** to facilitate gripping of rotatable knob **34**. Annular ring **116** permits rotation of knob **34** with respect to housing **22** while preventing axial movement with respect thereto. A pair of cylindrical rods **124** extend between half-sections **34***a* and **34***b* through a rectangular opening **126** formed in coupling member **98**. Rods **124** engage a pair of concave recesses **128** formed in fitting **130** which is fastened about vibration coupler **50**, such that rotation of knob **34** causes rotation of vibration coupler **50** and thus rotation of blade **58** and clamp **60**.

Alternately, recesses **128** can be monolithically formed with vibration coupler **50**.

FIGS. **7–10** illustrate ultrasonic instrument **12** with clamp **60** in the open position. The elongated body **24** which includes clamp **60** and blade **58**, and housing **22** which includes handles **28** and **36**, are packaged as an integral unit, e.g., non-detachably connected, that requires no assembly by the user prior to use. That is, the user needs only to attach transducer **30** to housing **22** to ready instrument **12** for use. In the open position, movable handle **36** is spaced rearwardly from stationary handle portion **28** and protrusions **90** are positioned in the lower proximal portion of cam slots **88**. At the distal end of ultrasonic instrument **12**, pivot members **66** are positioned near the distal end of guide slots **70** and camming members **72** are positioned in the upper distal portion of cam slots **74**. Tissue contact member **64** of clamp **60** is spaced from blade surface **59** to define a tissue receiving area **132**. The proximal end of tissue receiving area **132** is defined by tissue receiving stops **71** which are preferably integrally formed with clamp body **62** and extend below blade surface **59**. Preferably, the distal end of blade **58** is rounded to prevent inadvertent damage to tissue during use of instrument **12** and tissue contact surface **64** is also preferably formed with a longitudinally extending concavity **67** to receive tissue therein. Alternately, the distal end of blade **58** may be formed in any shape which may be suitable to a particular surgical application, i.e., pointed, flat, etc. Moreover, tissue contact surface **64** need not be formed with a concavity but may be flat, angled, etc.

Referring to FIGS. **11–15**, when movable handle **36** is pivoted clockwise about pivot member **82** towards stationary handle portion **28**, in the direction indicated by arrow "A" in FIG. **11**, cam slot **88** engages protrusion **90** of swivel member **108** to advance coupling member **98** distally within cavity **110** of rotation knob **34**. Since actuator tube **46** is attached to coupling member **98** by an annular flange **48**, actuator tube **46** is also advanced distally in the direction indicated by arrow "B" in FIG. **12**. Movement of actuator tube **46** distally causes cam slots **74** to move into engagement with camming members **72** to pivot clamp body **62** about pivot members **66**, in the direction indicated by arrow "C" in FIG. **13**, to move clamp member **62** and tissue contact member **64** into the clamped position. In the clamped position, protrusions **90** are located in a central portion of cam slots **88**, pivot members **66** are located near the proximal end of guide slots **70**, and camming members **72** are located in the proximal lower portion of cam slots **74**.

Elongated body portion **24** can be freely rotated with respect to housing **22** by rotating rotation knob **34**. As illustrated in FIG. **15**, rotation of knob **34** in the direction indicated by arrow "D" causes rotation of jaw assembly **32** in the direction indicated by arrow "E". Knob **34** is positioned adjacent housing **22** to facilitate one handed operation of both movable handle **36** and rotation knob **34**.

Referring again to FIG. **1**, elongated body portion **24** is dimensioned to extend through a trocar assembly **140**, and is preferably dimensioned to extend through a 5 mm trocar assembly. During use, elongated body portion **24** is slid through trocar assembly **140** with jaw assembly **32** in the clamped or closed position to a position adjacent tissue (not shown) to be dissected and/or coagulated. An optical unit (not shown) can also be positioned adjacent the surgical site to facilitate viewing of the procedure. Jaw assembly **32** is opened and tissue to be dissected and/or coagulated is positioned within tissue receiving area **132** (See also FIG. **9**). Tissue receiving stops **71** prevent tissue from moving past the proximal end of blade surface **59**. Next, jaw assembly **32** is closed to clamp tissue between tissue contact member **64** and blade surface **59**. Power is supplied to ultrasonic instrument **12** via control module **14** to initiate vibration of blade **58** to effect dissection and/or coagulation of tissue. Because of the curve of blade surface **59**, the force applied by blade surface **59** to the tissue being dissected can be selectively increased or decreased as instrument **12** is moved forward through trocar assembly **140** by adjusting the location of the tissue on blade surface **59** and thus changing the angle of the force applied to the tissue being dissected.

FIGS. **16A–16C** illustrate an alternate embodiment of the ultrasonic transducer shown generally as **230**. Ultrasonic transducer **230** includes a housing **231** having a proximal housing portion **232** and a distal housing portion **234**. Proximal housing portion **232** has a scalloped section **236** adjacent its proximal end. Transducer horn **238** is supported within housing **231** by support collar **240** and annular ring **242**. The distal end of transducer horn **238** includes a threaded bore **244** dimensioned to engage reduced diameter portion **54** of vibration coupler **50** (FIG. **4**). As best illustrated in FIG. **16B**, transducer horn **238** is formed with annular flange **246**, about which annular ring **242** is received. The proximal end of support collar **240** also includes an annular flange **248** which, in an assembled condition, is clamped between proximal and distal housing portions **232** and **234** to fixedly retain support collar **240** in position within housing **231**. The distal end of support collar **240** engages annular ring **242** to retain annular ring **242** and thus horn **238** in a longitudinally fixed position within housing **231**.

Referring to FIGS. **17A–17B**, torque wrench assembly **250** is configured and dimensioned to engage scalloped section **236** of ultrasonic transducer **230** to facilitate assembly of transducer assembly **230** with the remaining portion of ultrasonic instrument **12**. Torque wrench assembly **250** assures that horn **238** and vibration coupler **50** (FIG. **4**) are properly connected, i.e., properly torqued.

It will be understood that various modifications may be made to the embodiments herein. For example, vibration coupler **50** and blade **58** may be monolithically formed or attached using structure other than screw threads. Different actuator assemblies other than the actuator tube having a camming surface can be used to pivot the clamp member to the clamped position. Further, the elongated body portion of the instrument can be dimensioned to extend through other than 5 mm trocar assemblies, e.g., 10 mm, 12 mm, etc. Therefore, the above description should not be construed as limiting, but merely as exemplifications of preferred embodiments. Those skilled in the art will envision other modifications within the scope and spirit of the claims appended hereto.

What is claimed is:

1. An ultrasonic instrument comprising:

a) a vibration coupler;

b) a cutting jaw operatively connected to the vibration coupler;

c) a clamp member supported adjacent to the cutting jaw, the clamp member being moveable in relation to the cutting jaw between an open position in which at least a portion of the clamp member is spaced from the cutting jaw and a closed position in which the clamp member and the cutting jaw are in substantially juxtaposed alignment; and

d) a rotatable member operatively associated with the vibration coupler, the clamp member and the cutting jaw, the rotatable member being rotatable to cause corresponding rotation of the clamp member and cutting jaw about a longitudinal axis of the instrument.

2. An ultrasonic instrument according to claim **1**, wherein the cutting jaw includes a curved cutting surface.

3. An ultrasonic instrument according to claim **2**, wherein the curved cutting surface is convex.

4. An ultrasonic instrument according to claim **1**, wherein the clamp member includes a tissue contact surface removably fastened to the clamp member.

5. An ultrasonic instrument according to claim **1**, further including a handle assembly, the vibration coupler extending distally from the handle assembly, the handle assembly including a moveable handle operatively connected to the clamp member and being moveable to move the clamp member between the open and closed positions.

6. An ultrasonic instrument according to claim **1**, wherein the clamp member includes a pair of tissue engaging stops.

7. An ultrasonic instrument comprising:

a) a handle assembly;

b) a vibration coupler supported by and extending distally from the handle assembly;

c) a cutting jaw having a cutting surface operatively connected to the vibration coupler;

d) a clamp member supported adjacent to the cutting jaw, the clamp member and the cutting jaw defining a tissue receiving area, the clamp member being moveable between open and closed positions in relation to the cutting jaw and having a tissue engaging stop positioned to engage tissue and prevent positioning of tissue beyond the proximal end of the cutting surface of the cutting jaw.

8. An ultrasonic instrument according to claim **7**, further including an actuator tube slidably positioned about the vibration coupler, a distal end of the actuator tube including a cam slot configured to receive cam members formed on the clamp member, the actuator tube being moveable between advanced and retracted positions about the vibration coupler in response to actuation of the handle assembly to effect movement of the clamp member between the open and closed positions.

9. An ultrasonic instrument according to claim **8**, wherein the handle assembly includes a stationary handle and a moveable handle, the moveable handle being operably connected to a proximal end of the actuator tube.

10. An ultrasonic instrument according to claim **9**, further including a coupling member, the coupling member interconnecting the actuator tube and the moveable handle.

11. An ultrasonic instrument according to claim **10**, wherein the coupling member includes a swivel member, the swivel member being positioned to permit rotation of the coupling member in relation to the moveable handle.

12. An ultrasonic instrument according to claim **11**, wherein the coupling member is operably connected to a rotatable knob positioned adjacent the handle assembly, the rotatable knob being rotatably secured to the handle assembly such that rotation of the rotatable knob in relation to the handle assembly effects corresponding rotation of the coupling member and the clamp member.

13. An ultrasonic instrument according to claim **12**, wherein the vibration coupler is rotatably fixed to the rotatable knob such that rotation of the rotatable knob also effects corresponding rotation of the vibration coupler and the cutting jaw.

14. An ultrasonic instrument according to claim **8**, further including an outer tube positioned about the actuator tube, the clamp member being pivotally connected to the outer tube.

15. An ultrasonic instrument according to claim **7**, wherein the cutting surface of the cutting jaw is curved along the longitudinal axis of the instrument.

16. An ultrasonic instrument according to claim **15**, wherein the curved cutting surface is convex.

17. An ultrasonic instrument according to claim **7**, wherein the clamp member includes a tissue contact surface removably fastened to the clamp member.

18. An ultrasonic instrument according to claim **13**, wherein the cutting surface of the cutting jaw is convex along the longitudinal axis of the instrument.

19. An ultrasonic instrument according to claim **7**, wherein a transverse cross-section of the clamp member defines a concavity.

20. An ultrasonic instrument according to claim **19**, wherein a transverse cross-section of the cutting jaw defines a triangular shape having an apex, wherein the apex of the triangular shape is the cutting surface.

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